

EXHIBIT A-31



**ALICE STILLs, on her own behalf and
as Parent and Natural Guardian of
M.E., a Minor**

Plaintiff,

v.

**MEAD JOHNSON & COMPANY, LLC,
et al.,**

Defendants.

**PHILADELPHIA COUNTY COURT OF
COMMON PLEAS**

**MARCH TERM, 2022
No. 02617**

ORDER

AND NOW, this day of 2023, upon consideration of the Preliminary Objections of Defendants Mead Johnson & Company, LLC and Mead Johnson Nutrition Company (collectively, "Mead Johnson" or "Moving Defendants") to Plaintiffs' Complaint, and any Response thereto, it is hereby **ORDERED** that the Preliminary Objections are **SUSTAINED**. It is further **ORDERED** that all claims against Defendants Mead Johnson & Company, LLC and Mead Johnson Nutrition Company are hereby **DISMISSED** with prejudice.

BY THE COURT:

J.

**ALICE STILLLS, on her own behalf and
as Parent and Natural Guardian of
M.E., a Minor**

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1. Count I of Plaintiffs' Complaint is **DISMISSED** with prejudice;
2. Count II of Plaintiffs' Complaint is **DISMISSED** with prejudice;
3. Count III of Plaintiffs' Complaint is **DISMISSED** with prejudice;
4. Count IV of Plaintiffs' Complaint is **DISMISSED** with prejudice;
5. Count V of Plaintiffs' Complaint is **DISMISSED** with prejudice;
6. Plaintiffs' Complaint is **STRICKEN** for lack of specificity;
7. Plaintiffs' claims for punitive damages as to Defendants Mead Johnson & Company, LLC and Mead Johnson Nutrition Company are **DISMISSED** with prejudice, along with all allegations of oppressive, reckless, malicious and/or fraudulent conduct;
8. Plaintiff Alice Stills' claims in her own right are **DISMISSED** with prejudice; and

9. Plaintiffs' Complaint is **STRICKEN** for lack of an appropriate verification.

BY THE COURT:

J.

NOTICE TO PLEAD:

To Plaintiff: You are hereby notified to file a written response to the enclosed Preliminary Objections within twenty (20) days from service hereof or a judgement may be entered against you.

/s/ Kenneth A. Murphy
Attorney for Defendants, Mead Johnson & Company, LLC and Mead Johnson Nutrition Company

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COMPANY**

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**MARCH TERM, 2022
No. 02617**

**PRELIMINARY OBJECTIONS OF DEFENDANTS MEAD JOHNSON & COMPANY,
LLC AND MEAD JOHNSON NUTRITION COMPANY TO PLAINTIFFS' COMPLAINT**

Defendants Mead Johnson & Company, LLC and Mead Johnson Nutrition Company (hereinafter "Moving Defendants" or "Mead Johnson") hereby preliminarily object to Plaintiffs' Complaint, and, in support thereof, aver as follows:

I. INTRODUCTION

1. The case before the Court involves speculative and unsupported allegations by Plaintiffs that the minor Plaintiff, M.E., developed a condition known as necrotizing enterocolitis (“NEC”) following his alleged ingestion of Similac and/or Enfamil cow’s milk-based infant formula manufactured and sold by Moving Defendants and/or defendant Abbott Laboratories (“Abbott”). Plaintiffs fail to identify the particular product that M.E. purportedly ingested, and the entirety of Plaintiffs’ claims rest on their unsubstantiated conclusion that the formula consumed by M.E. is an unreasonably dangerous product. Plaintiffs acknowledge that premature infants such as M.E. have an inherent high risk of developing NEC. However, to support their theory of causation, Plaintiffs cite to certain literature that compares cow’s milk-based products to breast milk. None of the literature upon which Plaintiffs rely concludes that cow’s milk-based formula causes NEC. In fact, the articles carefully avoid that conclusion, saying only that breast milk may be protective against NEC. The Complaint is otherwise devoid of factual support for Plaintiffs’ claim that Mead Johnson’s product caused M.E. to develop NEC. Plaintiffs allege only that M.E. was born on a certain date; *may* have been provided one of Defendants’ infant formula products; and, at some point, developed NEC. But, Plaintiffs have failed to identify which Mead Johnson product the infant received; whether the infant received mother’s own milk; whether the infant received donor milk; how the infant came to receive Mead Johnson’s product; when M.E. ingested the product; when M.E. was diagnosed with NEC; what treatment was

provided for that condition; or what short- or long term- injury M.E. allegedly sustained. Plaintiffs nowhere allege how cow's milk purportedly *causes* NEC, or how the facts of M.E.'s case relate to the scientific evidence Plaintiffs cite. Pennsylvania's procedural rules do not allow for such gaps in logic and omissions of material facts in a complaint. Accordingly, Plaintiffs' Complaint should be dismissed.

2. Plaintiffs instituted this action via the filing of a Complaint on March 24, 2022, against Moving Defendants as well as Co-Defendant Abbott, The Pennsylvania Hospital of the University of Pennsylvania and The Trustees of the University of Pennsylvania ("HUP"). See Plaintiffs' Complaint, attached as Exhibit "A."

3. Plaintiffs have filed nearly 30 essentially identical lawsuits against Moving Defendants, Abbott, HUP, and other hospitals in Philadelphia based on claims relating to alleged ingestion of cow's milk-based infant formula by premature infants following their birth.

4. Plaintiffs allege that "upon information and belief" the Plaintiff-minors, including M.E., developed NEC, a gastrointestinal disorder that occurs in premature infants. See Plaintiffs' Complaint, attached as Exhibit "A," ¶ 13. Plaintiffs allege that premature infants fed with their mother's breast milk or donor breast milk are at decreased risk of developing NEC as compared with infants given cow's milk-based infant formula.

5. In addition to asserting product liability claims against Moving Defendants and Abbott, as the infant formula manufacturers, Plaintiffs have brought claims against The Pennsylvania Hospital of the University of Pennsylvania and The Trustees of the

University of Pennsylvania alleging liability on theories of failure to warn and corporate liability.

6. The factual background regarding the Plaintiff-minor's birth, diagnosis and injuries are limited to three (3) paragraphs in the Complaint.

7. Plaintiffs aver that M.E. was born prematurely September 28, 2007 and that "[u]pon information and belief M.E. was fed Similac and/or Enfamil cow's milk-based products by staff at Pennsylvania Hospital from shortly after his birth." *Id.*, ¶¶ 11-12.

8. Plaintiffs further allege that "upon information and belief" M.E. developed NEC shortly after first ingesting the Defendant manufacturers' products. *Id.*, ¶ 13.

9. Plaintiffs do not allege that M.E. suffered any specific injuries or long-term negative health effects.

10. Moving Defendants Preliminarily Object to Plaintiffs' Complaint for the reasons stated below and as more fully set forth in the accompanying Memorandum of Law, which is incorporated herein by reference.

II. ARGUMENT

A. DEMURRER FOR FAILURE TO STATE A CLAIM AS TO COUNTS I, II, III, IV, & V

11. Plaintiffs allege in Counts I and II of the Complaint that Moving Defendants, "as the manufacturers and/or sellers of the products at issue in this litigation" owed Plaintiffs and the public a duty to manufacture, sell, and distribute their products in a manner that was not unreasonably dangerous and to warn of unreasonable risk of harm posed by their products.

12. Plaintiffs allege in Count III (Negligence) of the Complaint that Moving Defendants, “as the manufacturers and/or sellers of the products at issue in this litigation” owed Plaintiffs and the public a duty to exercise reasonable care to design, test, manufacture, inspect, and distribute products that were free of unreasonable risk of harm.

13. Plaintiffs allege in Count IV (Intentional Misrepresentation) and Count V (Negligent Misrepresentation) of the Complaint that Moving Defendants, “as the manufacturers and/or sellers of the products at issue in this litigation” owed Plaintiffs and the public a duty to provide truthful, accurate, fulsome information about their cow’s milk-based products.

14. Counts I, II, III, IV, and V are based upon Plaintiffs’ theory against Moving Defendants that Moving Defendants’ cow’s milk-based products are unreasonably dangerous, and for strict liability purposes in Counts I & II, defective.

15. In support of their theories and claims, Plaintiffs cite to five studies comparing cow’s milk-based products to breast milk, a Surgeon General report on the subject, and a statement by the American Academy of Pediatrics. See Exhibit “A,” ¶¶ 16-22.

16. Taking these facts as pleaded by Plaintiffs as true, Plaintiffs have failed to state a claim for defective design and failed to state a claim for failure-to-warn, due to an absence of proof of that the products are indeed unreasonably dangerous.

17. As is discussed in detail in the accompanying Memorandum of Law, infant formulas are regulated by the United State Food and Drug Administration and are

required to include specified vitamins and nutrients, including infant formulas intended for low birth weight infants.

18. The FDA does not restrict the use of cow's milk-based infant formula for premature or low birth weight infants. Thus, Plaintiffs' contention that cow's milk-based infant formula should never be given to premature infants is not supported by the FDA.

19. "The law governing strict products liability actions in Pennsylvania has been developed based upon the principles outlined in Section 402A of the Second Restatement of Torts." *High v. Pennsy Supply, Inc.*, 154 A.3d 341 (Pa. Super. 2017).

Section 402(A) provides:

- (1) One who sells any product in a defective condition unreasonably dangerous to the user or consumer or to his property is subject to liability for physical harm thereby caused to the ultimate user or consumer, or to his property, if
 - (a) the seller is engaged in the business of selling such a product, and
 - (b) it is expected to and does reach the user or consumer without substantial change in the condition in which it is sold.
- (2) The rule stated in Subsection (1) applies although
 - (a) the seller has exercised all possible care in the preparation and sale of his product, and
 - (b) the user or consumer has not bought the product from or entered into any contractual relation with the seller.

Restatement (Second) of Torts § 402(A).

20. To survive preliminary objections, Plaintiffs must aver sufficient facts, together with the documents and exhibits attached thereto, to make out a *prima facie*

case as to all elements of the cause of action. *Northern Forests II, Inc. v. Keta Realty Co.*, 130 A.3d 19, 35 (Pa. Super. 2015).

21. “The threshold inquiry in all products liability cases is whether there is a defect which rendered the product unreasonably dangerous.” *Weiner v. American Honda Motor Co., Inc.*, 718 A.2d 305, 307 (Pa. Super. 1998). “A product is defective when it is not safe for its intended use, i.e., the product left the supplier's control lacking any element necessary to make it safe for its intended use.” *Id.* at 308. Whether a product is “unreasonably dangerous” is a question of law. *Id.*

22. Based on the foregoing, the threshold Plaintiffs must cross as to Counts I, II, III, IV, and V, is that Plaintiffs must aver sufficient facts demonstrating the Moving Defendants’ products are unreasonably dangerous for their intended use, triggering the duties set forth in Plaintiffs’ Complaint at Counts I, II, III, IV, and V.

23. Although Plaintiffs cite in their Complaint to research studies relating to the purported risks of cow’s milk-based products in premature infants, the studies demonstrate only, assuming the facts as true as stated by Plaintiffs, that premature infants are at high risk of NEC, and that feeding such infants with breast milk may be better at reducing the risk of NEC than cow’s milk-based alternatives. See Exhibit “A,” ¶¶ 16-22.

24. At the outset, Plaintiffs appropriately acknowledge that “[p]reterm and low-birth-weight infants are *especially susceptible* to NEC.” See Exhibit “A” at ¶ 15 (emphasis added).

25. Following this, Plaintiffs make the core claim of their Complaint – that cow’s milk-based feeding products cause NEC in preterm and low birth weight infants –

and that “[e]xtensive scientific research, including numerous randomized controlled trials” confirm this claim. *Id.* However, the portions of the research and trials cited by Plaintiffs in their Complaint belie their core claim.

26. The first study cited by Plaintiffs states, according to the Complaint, that “NEC was six to ten times *more common* in exclusively cow’s milk formula-fed babies than in exclusively breast milk-fed babies and three times more common in babies who received a combination of formula and breast milk.” *Id.* at ¶ 17 (emphasis added). To say that NEC is more common in infants fed cow’s milk-based products than those fed breast milk is to say that NEC **still occurs in infants fed exclusively breast milk**, but only at a lower rate. Thus, Plaintiffs’ first study does not state cow’s milk-based feeding products causes NEC. Indeed, the study itself¹ explains that the difference in NEC incidence may be mediated by the protective effects of immunoglobulin in breast milk, which, when added to formula, also protected against NEC: “We suggest, in the light of the finding that oral immunoglobulin in formula fed babies was prophylactic, that breast milk may protect against necrotizing enterocolitis by providing IgA in the gut lumen.” Lucas, et al., *Breast Milk and Neonatal Necrotizing Enterocolitis*, 336 LANCET 1519, 1522 (1990). The article goes on to *recommend* the concomitant use of bovine formulas to meet the increased nutritional needs of premature infants. *Id.*

¹ For the Court’s convenience, Moving Defendants have attached as Exhibit “B” a copy of A. Lucas, et al., *Breast Milk and Neonatal Necrotizing Enterocolitis*, 336 LANCET 1519-1523 (1990), which is the first study that Plaintiffs quote from, and rely on, in their Complaint, but have failed to attach. Where a plaintiff has averred the existence of certain written documents and premised a cause of action upon those documents, it is proper in Pennsylvania for a defendant to attach those documents in support of a demurrer. *See Richardson v. Wetzel*, 74 A.3d 353, 358 n.4 (Pa. Commw. Ct. 2013). As Plaintiffs in the instant matter rely extensively on this and other studies to prove their theory of causation, Moving Defendants have properly attached them here for the Court’s consideration.

27. As averred in the Complaint, the second study cited by Plaintiffs states that “preterm babies fed an exclusive breast milk-based diet were 90% less likely to develop surgical NEC (NEC that requires surgical treatment), compared to preterm babies fed a diet that included some cow’s milk-based products.” *Id.* at ¶ 18. To state that preterm infants fed only breast milk are **less likely** to develop a form of NEC is to admit that NEC still develops in preterm infants **regardless of the diet**. Thus, Plaintiffs’ second study likewise does not state that cow’s milk-based feeding products cause NEC. To the contrary, it too posits that breast milk is simply protective: “These data suggest that exclusive human diets may exert protective, rather than threshold, effects with respect to NEC.” Sandra Sullivan, et al., *An Exclusively Human Milk-Based Diet is Associated with a Lower Rate of Necrotizing Enterocolitis than a Diet of Human Milk and Bovine Milk-Based Products*, 4 J. PEDIAT. 562, 566 (2010), a true and correct copy of which is attached hereto as Exhibit “C.”

28. The third study cited by Plaintiffs concluded, per the Complaint, “fortification of breast milk with a cow’s milk-based fortifier resulted in a 4.2-fold increased risk of NEC and a 5.1-fold increased risk of surgical NEC or death, compared to fortification with a breast milk-based fortifier.” *Id.* at ¶ 19. What the study does not state, as alleged in the Complaint, is that cow’s milk-based fortifiers cause NEC.

29. The Surgeon General report cited by Plaintiffs is alleged in the Complaint to reiterate the principle made in the prior three studies and states that “formula feeding is associated with *higher rates*” of NEC in preterm infants and that “premature infants who are not breastfed are 138% more likely to develop NEC.” *Id.* at ¶ 20 (emphasis added). If cow’s milk-based formula caused NEC as Plaintiffs aver, one might expect

the Surgeon General report to so state. Instead, the Surgeon General report, as described in Plaintiffs' Complaint at ¶ 20, makes the same acknowledgment as Plaintiffs – that preterm infants are highly susceptible to NEC regardless of their diet, and that NEC occurs in different rates in preterm infants fed cow's milk-based products and breast milk. The report does not state that the former causes NEC.

30. According to the Complaint, the American Academy of Pediatrics makes a nearly identical statement to the Surgeon General report. *Id.* at ¶ 21. The Academy makes a recommendation that "all premature infants should be fed either their mother's milk or, if their mother's milk is unavailable, pasteurized donor milk," which recommendation is alleged to be related in part to "lower rates... of NEC." *Id.* This statement acknowledges that NEC still occurs in preterm infants fed only breast milk, but simply at a lower rate. According to the Complaint, the Academy does not state that cow's milk-based feeding products cause NEC. Instead, as quoted by Plaintiffs, the statement touts the potent protective effects of breastmilk.

31. The fourth and fifth studies cited by Plaintiffs in their Complaint provide similar information. As alleged in the Complaint, a study "found that premature and low-birth-weight infants fed an exclusive breast milk-based diet suffered NEC only 3% of the time while premature and low-birth-weight infants receiving cow's milk-based formula suffered NEC 21% of the time." In another study, as alleged in the Complaint, "babies given exclusively breast milk products suffered NEC 5% of the time," whereas "babies given cow's milk products suffered NEC 17% of the time." *Id.* at ¶¶ 22-23. Once again, these studies, based on the allegations in Plaintiffs' Complaint, do not state that cow's milk-based formula causes NEC.

32. Thus, all of the studies identified and quoted by Plaintiffs undercut Plaintiffs' allegations that cow's milk-based products cause NEC and do not support Plaintiffs' contention that such products are unreasonably dangerous.

33. The numerous studies and reports cited by Plaintiffs in their Complaint purportedly show higher rates of NEC in preterm and low birth weight infants fed cow's milk-based diets than those fed breast milk, but this data exists in a world where Plaintiffs admit these infants are at a high risk of developing NEC regardless of diet.

34. All that Plaintiffs' Complaint demonstrates, as pleaded under these facts, is that breast milk may be protective against the risk of NEC, not that cow's milk-based alternatives affirmatively cause NEC. This proposition does not make the Moving Defendants' cow's milk-based alternatives unreasonably dangerous within the meaning of § 402(A) of the Restatement (Second) of Torts.

35. Thus, Plaintiffs' Complaint fails to aver sufficient facts to demonstrate that Moving Defendants' products are indeed unreasonably dangerous. Consequently, Plaintiffs' Complaint should be stricken at Counts I, II, III, IV, and V for failure to state a claim.

B. DEMURRER FOR FAILURE TO STATE A CLAIM AS TO COUNTS IV & V

36. Counts IV and V of Plaintiffs' Complaint allege intentional and negligent misrepresentation, respectively, against Moving Defendants. Plaintiffs cannot maintain misrepresentation claims because they fail to allege that they received any specific representation from Moving Defendants on which they relied. In fact, as they have not even alleged that M.E. received a Mead Johnson product, they cannot claim that misrepresentations by Mead Johnson caused reliance or their purported injury.

37. The elements of a claim for negligent misrepresentation are: “(1) a misrepresentation of a material fact; (2) made under circumstances in which the misrepresenter ought to have known its falsity; (3) with an intent to induce another to act on it; and (4) which results in injury to a party acting in justifiable reliance on the misrepresentation.” *Bilt-Rite Contractors v. Architectural Studio*, 866 A.2d 270, 277 (Pa. 2005) (quoting *Bortz v. Noon*, 556 Pa. 489, 729 A.2d 555, 561 (Pa. 1999)). Negligent misrepresentation differs from intentional misrepresentation “in that the misrepresentation must concern a material fact and the speaker need not know his or her words are untrue, but must have failed to make a reasonable investigation of the truth of these words.” *Bortz*, 729 A.2d at 561.

38. The elements of an intentional misrepresentation claim require: “(1) A representation; (2) which is material to the transaction at hand; (3) made falsely, with knowledge of its falsity or recklessness as to whether it is true or false; (4) with the intent of misleading another into relying on it; (5) justifiable reliance on the misrepresentation; and (6) the resulting injury was proximately caused by the reliance.” *Bortz*, 729 A.2d at 499 (citing *Gibbs v. Ernst*, 647 A.2d 882, 889 (1994), citing, Restatement (Second) of Torts § 525 (1977)).

39. Here, Plaintiffs’ claims fail to allege that they received any specific representation from Moving Defendants, intentional or otherwise. Plaintiffs further fail to allege that they relied on a specific representation of the Moving Defendants.

40. Because of these omissions from Plaintiffs’ Complaint, Plaintiffs have failed to articulate a viable claim for intentional and negligent misrepresentation. See, e.g., *Cruz v. Roberts*, No. CI-04-01947, 2005 Pa. Dist. & Cnty. Dec. LEXIS 186, 70 Pa.

D. & C.4th 225 (Pa. CCP Jan. 26, 2005) (dismissing negligent and intentional misrepresentation claims for insufficient pleading); see also *Kepner v. Tine*, No. 835 EDA 2015, 2015 Pa. Super. Unpub. LEXIS 4257 (Pa. Super. Nov. 25, 2015) (dismissing fraudulent misrepresentation claim for failure to plead a particular misrepresentation).

41. Thus, Plaintiffs' intentional and negligent misrepresentation claims against Moving Defendants must be dismissed.

C. MOTION TO STRIKE PLAINTIFFS' COMPLAINT FOR INSUFFICIENT SPECIFICITY AS TO THE FACTS AND ALLEGED INJURIES

42. Pursuant to Pa.R.C.P. 1028(a)(3), a party may file preliminary objections in the nature of a motion to strike for insufficient specificity in a pleading.

43. A plaintiff's Complaint is required to provide a defendant with notice of what the plaintiff's claims are and the grounds upon which they rest, and the Complaint must also formulate the issues by summarizing the facts essential to support the claims. *Alpha Tau Omega Fraternity v. The University of Pennsylvania*, 464 A.2d 1349, 1352 (Pa. Super. 1983) (citations omitted).

44. Pennsylvania Rule of Civil Procedure 1019(a) provides that "the material facts on which a cause of action or defense is based shall be stated in a concise and summary form." Pa.R.C.P. 1019(a). As the Superior Court has noted,

Rule 1019(a) requires fact pleading. The purpose of 1019(a) is to require the pleader to disclose the material facts sufficient to enable the adverse party to prepare his case. **A complaint therefore must do more than give the defendant fair notice of what the plaintiff's claim is and the grounds upon which it rests. It should formulate the issues by fully summarizing the material facts. Material facts are ultimate facts, i.e., those facts essential to support the claim. Evidence from which such facts may be inferred not only need not but should not be alleged. Allegations will withstand challenge under 1019(a) if (1)**

they contain averments of all of the facts a plaintiff will eventually have to prove in order to recover, and (2) they are sufficiently specific so as to enable defendant to prepare his defense.

Baker v. Rangos, 324 A.2d 498, 505-506 (Pa. Super. 1974) (citations and internal quotations omitted) (emphasis added).

45. Further, it is well established that, with regard to the description of injuries sustained by a plaintiff, the Complaint must be stated with sufficient particularity to put the defendant on notice of evidence that may be produced at trial. *Kelly v. Martino*, 99 A.2d 901 (Pa. 1953). **A plaintiff's Complaint must set forth the extent, nature, location and duration of the injuries suffered, and injuries that are permanent should be stated specifically.** *Miller v. Perrige*, 71 Pa. D. & C.2d 476, 479–80 (Pa. Com. Pl. 1975). *See, also, Kopan v. Hawk*, 14 Pa. D. & C.2d 713, 714 (Pa. Com. Pl. 1958) (“A catchall averment of “other injuries” is nothing more than a generalized averment under which any injuries whatever could be proved at the trial. Defendant would have no knowledge in advance of the trial of what they are.”)

46. Plaintiffs' Complaint is facially deficient with regard to the specificity of the allegations of the relevant facts and injuries at issue in this case.²

47. Plaintiffs' description of the material facts relating to the minor's care and treatment, diagnosis and injuries is limited to four paragraphs, which are utterly insufficient to enable defendants to prepare their defenses. *See* Exhibit “A,” ¶¶ 11-13.

48. Plaintiffs aver that the minor was born prematurely but do not identify the gestational age at which the child was born or his birth weight. Plaintiffs' allegation that

² Access to the relevant medical records **before** filing suit would have allowed Plaintiffs to comport themselves consistently with Rule 1019(a). Given that minor plaintiff's purported claims are tolled until age of majority, no good reason exists for Plaintiffs' failure to support their complaint with required facts.

“upon information and belief,” the minor was fed Similac and/or Enfamil shortly after his birth (*Id.* at ¶ 12) does not comply with the fact-pleading requirements of Rule 1019(a), since such allegations do not provide Moving Defendants with appropriate notice of the facts as to whether the minor actually ingested cow’s milk-based products.

49. Further, Plaintiffs have failed to identify which of the numerous products sold by Abbott and Mead Johnson under the Similac and Enfamil brand names were ingested by the minor. *Id.* at ¶¶ 37-38.

50. Plaintiffs’ Complaint further fails to provide a description of the material facts as to the period of time in which such products were ingested, when the minor was allegedly diagnosed with NEC and what treatment was provided for that condition.

51. The Complaint further fails to state the nature of the injuries and “long-term health effects” that are alleged to have resulted from the diagnosis of NEC.

52. Plaintiffs’ damages claim is not stated with particularity, is amorphous, vague, and open-ended. Pursuant to Pennsylvania pleading requirements, Moving Defendants should not be compelled to defend a claim for which the statement of injury is unspecified and subject to change.

53. These omissions are fatal defects in Plaintiff’s Complaint. Therefore, Plaintiffs’ Complaint should be stricken in its entirety.

D. MOTION TO STRIKE PLAINTIFFS’ CLAIMS FOR PUNITIVE DAMAGES

54. In the *Ad Damnum* clauses of Counts I, II, III, IV, and V of the Complaint, Plaintiffs make baseless accusations that Moving Defendants engaged in oppressive, reckless, malicious and/or fraudulent conduct that allegedly justify an award of punitive damages. See Exhibit “A,” pp. 22, 25, 28, and 31.

55. However, the Complaint contains no specific allegations of conduct that would permit recovery of punitive damages as to Moving Defendants.

56. Rather, Plaintiffs merely allege that “upon information and belief” M.E. may have been given a cow’s milk-based infant formula following birth, absent any context to indicate that such an action was inappropriate based on the specific issues involved in M.E.’s medical care and condition following birth.

57. For example, the Complaint gives no indication of whether Plaintiff-parent refused or was unable to provide breast milk and provides no information as to discussions between her and any health care providers regarding the purported use of cow’s milk-based products.

58. Plaintiffs’ allegations of oppressive, malicious and similar conduct must be rejected as mere boilerplate. As discussed above, the FDA specifically approves the use of infant formula in care of low birth weight infants, with no restriction as to the use of cow’s milk-based products for such infants.

59. Indeed, the fact that Plaintiffs have filed numerous lawsuits against at least four other hospitals in Philadelphia based on identical claims belies the contention that Moving Defendants engaged in outrageous or malicious conduct in allegedly feeding the Plaintiff-minor with cow’s milk-based infant formula.

60. Absent specific factual allegations to justify the claim that the use of infant formula in M.E.’s case was extreme and outrageous, there is no basis for an award of punitive damages in this case.

61. Merely contending that punitive damages should be awarded with no supporting factual justification requires dismissal of this claim.

62. Since the purpose of punitive damages is not compensation of a plaintiff but punishment of the defendant and deterrence, punitive damages can be awarded only for conduct involving some element of outrage. *Hutchinson v. Luddy*, 582 Pa. 114, 870 A.2d 766 (2005). For that reason, Pennsylvania Supreme Court decisions establish that “punitive damages are an ‘extreme remedy’ available in only the most exceptional matters.” *Wagner v. Onofrey*, 2006 Pa. Dist. & Cnty. Dec. LEXIS 333, *11 (Pa. Com. Pl. 2006) (citing *Phillips v. Cricket Lighters*, 584 Pa. 179, 188, 883 A.2d 439, 445 (2005)). “In fact, punitive damages are specifically designed to heap an additional punishment on a defendant who is found to have acted in a fashion which is particularly egregious.” *Wagner* at *12.

63. Punitive damages may not be awarded for misconduct that constitutes ordinary negligence such as inadvertence, mistake and errors of judgment. *Martin v. Johns-Manville Corp.*, 494 A.2d 1088, 1097 (Pa. 1985); *McDaniel v. Merck, Sharp & Dohme*, 533 A.2d 436, 437 (Pa. Super. 1987). An award of punitive damages must be supported by evidence of conduct more serious than the mere commission of the underlying tort. *Allstate Ins. Co. v. A.M. Pugh Assoc., Inc.*, 604 F. Supp. 85, 99 (M.D. Pa. 1984).

64. The Supreme Court has made clear that when assessing the propriety of the imposition of punitive damages, “the state of mind of the actor is vital. The act or failure to act, must be intentional, reckless or malicious.” *Hutchinson, supra* at 770. An appreciation of the risk is a necessary element of the mental state required for the imposition of punitive damages. *Id.* at 772.

65. Thus, “a punitive damages claim must be supported by evidence sufficient to establish that (1) a defendant had a subjective appreciation of the risk of harm to which the plaintiff was exposed and that (2) he acted, or failed to act, as the case may be, in conscious disregard of that risk.” *Id.*

66. Where the facts as averred show nothing more than negligence, a lapse in judgment, or mere inadvertence, courts in Pennsylvania have dismissed pleas and claims for punitive damages, often at the pleadings stage of litigation and even if the complaint alleged severe injuries or death. *See, e.g., Brownawell v. Bryan*, 40 Pa. D. & C.3d 604, 606 (Pa. Com. Pl. 1985) (dismissing punitive damages claim where a plaintiff alleged that a physician negligently performed a spinal fusion surgery that left the plaintiff with severe neurological defects, and noting that “**the mere pleading of outrageous conduct** does not, of course, satisfy the requirement stating facts which, if proven, would form a basis for a jury concluding that the conduct was such that an award of punitive damages was warranted.”) (emphasis added); *Wagner, supra* at *11 (contentions that physician failed to prescribe antibiotics, order certain tests or request an infectious disease consult constituted “nothing more than ordinary negligence and are insufficient to support an award of punitive damages.”); *McCardle v. Aldinger*, 5 Pa. D. & C.4th 421, 428 (Pa. Com. Pl. 1996) (sustaining preliminary objections and dismissing claim for punitive damages where the plaintiff alleged negligence in the prenatal care of her child that led to the child was stillborn and holding that “[i]t is not the outcome of the alleged negligence that is of consideration, but rather the alleged conduct of defendants that is at issue.”); *Flurer v. Pocono Medical Ctr.*, 15 Pa. D. & C.4th 645, 670 (Pa. Com. Pl. 1992) (sustaining preliminary objections and finding that

plaintiffs were not “capable of pleading the requisite behavior” for an award of punitive damages where a hospital allegedly failed to properly utilize a fetal monitor on a pregnant woman who was involved in a serious car accident and thereafter delivered a stillborn child).

67. Conversely, punitive damages have been reserved for those situations that are truly egregious and utterly outrageous, and typically involve aggravating or other factors that evince a particularly reckless mind or evil motive. See, e.g., *Medvecz v. Choi*, 569 F.2d 1221, 1227-30 (3rd Cir. 1987) (anesthesiologist who abandoned patient on operating room table and left room for a lunch break without securing a suitable replacement could be liable for punitive damages to patient who suffered irreversible paralysis from anesthesia complication that developed during his absence); *Hoffman v. Memorial Osteopathic Hospital*, 492 A.2d 1382, 386-87 (Pa. Super. 1985) (evidence that emergency room physician allowed Guillain-Barre Syndrome patient suffering from neurological paralysis to remain crying and immobile on floor for two hours as physician repeatedly stepped over patient was sufficient to support punitive damages claim); *Guernsey v. County Living Personal Care Home, Inc.*, 2006 U.S. Dist. LEXIS 31450, 2006 WL 1412765 (M.D. Pa. 2006) (punitive damages recoverable from nursing home officials who allowed resident to have access to room of 86-year old Alzheimer’s patient where he repeatedly raped her, since nursing home was aware of resident’s prior criminal convictions for sex registration as a sexual offender under Megan’s Law, and his prior instances of grabbing and kissing staff); *Lawrence v. Kunkle*, 75 D. & C. 4th 370 (Pa. Com. Pl. 2005) (patient could maintain punitive damages claim against physician who refused to perform emergency surgery because

patient did not have medical insurance even though physician knew that patient would likely suffer permanent neurologic and functional deficits if surgery was delayed).

68. All of the cases in the paragraph above set forth examples of egregious conduct, completely inapposite to the facts of the instant case.

69. The facts underlying Plaintiffs' bare assertions of oppressive, reckless, malicious and fraudulent conduct do not even remotely meet the requisite standard under Pennsylvania law that would permit an award of punitive damages. Without any factual support, the conclusory allegation that Moving Defendants was reckless is insufficiently pled and must be stricken with prejudice as to Moving Defendants, along with all allegations of reckless and similar conduct.

E. MOTION TO STRIKE PLAINTIFF-PARENT'S CLAIMS

70. Plaintiff-parent seeks to recover damages in her own right and as the parent and natural guardian of M.E.

71. Plaintiffs' Complaint includes allegations in each count against Moving Defendants in which it is averred that Plaintiff-parent "suffered significant emotional distress, loss of income, and/or other harms. Her life has been significantly affected by the Injured Infant's injuries." See Exhibit "A," ¶¶ 74, 82, 91, 101, 111, 125, 138, 146.

72. However, no specific cause of action is asserted as to any damages sought on behalf of Plaintiff-parent, who is not alleged in the Complaint to have suffered any physical injuries as a result of the alleged conduct of Moving Defendants. For this reason, Plaintiff-parent's claim should be dismissed.

73. Further, even if Plaintiff-parent had properly articulated a cause of action in the Complaint to allow her to recover damages in her own right, the Complaint should be stricken pursuant to Pa.R.C.P. 1020(b), which provides as follows:

If persons join as plaintiffs under Rules 2228, 2229(a) or (e), the complaint shall state the cause of action, any special damage, and the demand for relief of each plaintiff in a separate count, preceded by a heading naming the parties to the causes of action therein set forth.

74. Accordingly, it is improper for Plaintiffs to plead in a single count their claims on behalf of both the Plaintiff-minor and the Plaintiff-parent, as was done in the instant Complaint. Claims on behalf of each of the Plaintiffs must be set forth in separate counts of the Complaint, specifically identifying the cause of action asserted and relief sought in each count.

75. Additionally, although the statute of limitations for claims asserted on behalf of minors are tolled until the age of majority, Plaintiff-parent's claims were not similarly tolled and were required to have been brought within two years of the alleged injury. *See Fanscali ex rel. Fanscali v. Univ. Health Center of Pittsburgh*, 563 Pa. 439 (2000); *Hathi v. Krewstown Park Apts*, 561 A.2d 1261 (Pa. Super. 1989); 42 Pa.C.S. § 5524.

76. Plaintiffs allege that M.E. was born on September 28, 2007, was fed Similac and/or Enfamil cow's milk-based products shortly after his birth at Pennsylvania Hospital, and developed NEC shortly thereafter. See Exhibit "A," ¶¶ 11-13.

77. Thus, because Plaintiffs filed the Complaint at issue on March 24, 2022, Plaintiff-parent's claims herein are clearly time-barred based on the applicable statute of limitations and must be dismissed.

**F. MOTION TO STRIKE PLAINTIFFS' COMPLAINT FOR FAILURE TO
COMPLY WITH Pa.R.C.P. 1024**

78. Pennsylvania Rule of Civil Procedure 1024(a) requires verification of every pleading containing a factual averment based upon the signer's personal knowledge or information and belief.

79. Rule 1024(c) requires that the verification be made by one or more of the parties filing the pleading.

80. In this case, Plaintiffs' counsel signed the verification for the Complaint, in violation of Rule 1024. See Exhibit "A."

81. Accordingly, the Complaint should be stricken for lack of an appropriate verification.

WHEREFORE, Defendants Mead Johnson & Company, LLC and Mead Johnson Nutrition Company respectfully request that this Honorable Court sustain the instant Preliminary Objections and enter the attached proposed Order.

Respectfully submitted,

TUCKER LAW GROUP, LLC

Dated: June 15, 2023

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MEAD JOHNSON & COMPANY, LLC,
AND MEAD JOHNSON NUTRITION
COMPANY**

**ALICE STILLS, on her own behalf and
as Parent and Natural Guardian of
M.E., a Minor**

Plaintiff,

v.

**MEAD JOHNSON & COMPANY, LLC,
et al.,**

Defendants.

**PHILADELPHIA COUNTY COURT OF
COMMON PLEAS**

**MARCH TERM, 2022
No. 02617**

**MEMORANDUM OF LAW IN SUPPORT OF PRELIMINARY OBJECTIONS OF
DEFENDANTS MEAD JOHNSON & COMPANY, LLC AND MEAD JOHNSON
NUTRITION COMPANY TO PLAINTIFFS' COMPLAINT**

I. MATTER BEFORE THE COURT

Preliminary Objections of Defendants Mead Johnson & Company, LLC and Mead Johnson Nutrition Company (collectively, "Mead Johnson" or "Moving Defendants") to Plaintiffs' Complaint.

The case before the Court involves speculative and unsupported allegations by Plaintiffs that the minor Plaintiff, M.E., developed a condition known as necrotizing enterocolitis ("NEC") following his alleged ingestion of Similac and/or Enfamil cow's milk-based infant formula manufactured and sold by Moving Defendants and/or defendant Abbott Laboratories ("Abbott"). Plaintiffs fail to identify the particular product

that M.E. purportedly ingested, and the entirety of Plaintiffs' claims rest on their unsubstantiated conclusion that the formula consumed by M.E. is an unreasonably dangerous product. Plaintiffs acknowledge that premature infants such as M.E. have an inherent high risk of developing NEC. However, to support their theory of causation, Plaintiffs cite to certain literature that compares cow's milk-based products to breast milk. None of the literature upon which Plaintiffs rely concludes that cow's milk-based formula causes NEC. In fact, the articles carefully avoid that conclusion, saying only that breast milk may be protective against NEC. The Complaint is otherwise devoid of factual support for Plaintiffs' claim that Mead Johnson's product caused M.E. to develop NEC. Plaintiffs allege only that M.E. was born on a certain date; *may* have been provided one of Defendants' infant formula products; and, at some point, developed NEC. But, Plaintiffs have failed to identify which Mead Johnson product the infant received; whether the infant received mother's own milk; whether the infant received donor milk; how the infant came to receive Mead Johnson's product; when M.E. ingested the product; when M.E. was diagnosed with NEC; what treatment was provided for that condition; or what short- or long term- injury M.E. allegedly sustained. Plaintiffs nowhere allege how cow's milk purportedly *causes* NEC, or how the facts of M.E.'s case relate to the scientific evidence Plaintiffs cite. Pennsylvania's procedural rules do not allow for such gaps in logic and omissions of material facts in a complaint. Accordingly, Plaintiffs' Complaint should be dismissed.

II. STATEMENT OF QUESTIONS PRESENTED

1. Whether this Honorable Court should dismiss Count I of Plaintiffs' Complaint "Strict Liability for Design Defect" cause of action with prejudice because

Plaintiffs' Complaint does not support the claim that cow's milk-based products are unreasonably dangerous, and Moving Defendants cannot be held liable for a defective design?

Suggested Answer in the affirmative.

2. Whether this Honorable Court should dismiss Count II of Plaintiffs' Complaint "Strict Liability for Failure to Warn" cause of action with prejudice because Plaintiffs' Complaint does not support the claim that cow's milk-based products are unreasonable dangerous, and Moving Defendants cannot be held liable for failure-to-warn?

Suggested Answer in the affirmative.

3. Whether this Honorable Court should dismiss Count III of Plaintiffs' Complaint "Negligence" cause of action with prejudice on the basis of absence of proof of an unreasonably dangerous product?

Suggested Answer in the affirmative.

4. Whether this Honorable Court should dismiss Count IV of Plaintiffs' Complaint "Intentional Misrepresentation" cause of action with prejudice on the basis of absence of proof of an unreasonably dangerous product, and failure to plead any specific representation allegedly relied upon by Plaintiffs?

Suggested Answer in the affirmative.

5. Whether this Honorable Court should dismiss Count V of Plaintiffs' Complaint "Negligent Misrepresentation" cause of action with prejudice on the basis of absence of proof of an unreasonably dangerous product, and failure to plead any specific representation allegedly relied upon by Plaintiffs?

Suggested Answer in the affirmative.

6. Whether this Honorable Court should strike Plaintiffs' Complaint in its entirety for insufficient specificity of the facts and alleged injuries?

Suggested Answer in the affirmative.

7. Whether this Honorable Court should strike Plaintiffs' claims for punitive damages as to Moving Defendants because the Complaint fails to plead facts providing a basis for an award of punitive damages?

Suggested Answer in the affirmative.

8. Whether this Honorable Court should strike Plaintiffs' Complaint for failure to provide a client verification as required by Pa.R.C.P. 1024?

Suggested Answer in the affirmative.

III. INTRODUCTION AND FACTUAL BACKGROUND

Plaintiffs have filed nearly 30 essentially identical lawsuits against Moving Defendants and Abbott in Philadelphia based on claims relating to alleged ingestion of cow's milk-based products by premature infants in the hospital following their birth.¹ Plaintiffs allege that the Plaintiff-minors, including M.E., developed NEC, a gastrointestinal disorder that occurs in premature infants. See Plaintiffs' Complaint, attached as Exhibit "A" at ¶ 13. Plaintiffs aver that premature infants fed with their mother's breast milk or donor breast milk are at decreased risk of developing NEC as compared with infants given cow's milk-based products (infant formula). Many of the allegations of the Complaint are pleaded "upon information and belief," including the

¹ Lawsuits involving identical claims have been filed against Pennsylvania Hospital, Temple University Hospital, Albert Einstein Medical Center and Thomas Jefferson University Hospital.

allegations that Plaintiff-minors actually received infant formula, and that they developed NEC shortly after being fed with infant formula.

In addition to asserting product liability claims against Moving Defendants and Co-Defendant, Abbott, Plaintiffs have alleged that the Pennsylvania Hospital of the University of Pennsylvania and the Trustees of the University of Pennsylvania (“HUP”) are liable based on claims of failure to warn and corporate liability. See Plaintiffs’ Complaint at Counts VI and VII. As is discussed in detail below Plaintiffs’ claims against Moving Defendants are legally and factually deficient.

Although Plaintiffs aver that NEC is caused by cow’s milk-based products, Plaintiffs refer in their Complaint to research studies and reports that, as alleged by Plaintiffs, indicate only that NEC is more common in premature and low birth weight infants fed with cow’s milk-based products as compared with similar infants fed with breast milk. See Exhibit “A” at ¶¶ 16-22. As discussed in detail, *infra*, assuming the truth of the factual allegations stated in Plaintiffs’ Complaint, the research studies cited by Plaintiffs do not support the conclusion that cow’s milk-based formula causes NEC. In fact, the authorities they cite avoid that conclusion. As such, there is no basis to contend that cow’s milk-based products are unreasonably dangerous for premature infants.

Plaintiffs’ Complaint provides scant information regarding M.E.’s own circumstances. Plaintiffs aver that M.E. was born prematurely on September 28, 2007 and that “[u]pon information and belief M.E. was fed Similac and/or Enfamil cow’s milk-based products by staff at Pennsylvania Hospital shortly after his birth.” *Id.* at ¶ 12. Plaintiffs further allege that “upon information and belief” M.E. developed NEC shortly after first ingesting the Moving Defendants and Co-Defendant Abbott’s products. *Id.*, ¶

13. Plaintiffs provide no details regarding the extent of M.E.'s prematurity, his birth weight, or his condition following birth other than that she developed NEC on an unidentified date. Further, Plaintiffs allege no facts as to whether Plaintiff-parent provided breast milk to M.E., whether she had the opportunity to use donor milk, and if M.E. actually received a cow's milk product, what it was, how much, and for how long.² Finally, the Complaint is silent as to the nature and extent of M.E.'s alleged injuries.

Further, the Complaint does not provide any details whatsoever regarding communications between Plaintiff-parent and medical providers at HUP regarding the allegations that M.E. may have been fed with Mead Johnson and/or Abbott cow's milk-based products in the hospital. Plaintiffs conceded in the Complaint that mothers are encouraged by their healthcare professionals to breastfeed. *Id.* ¶ 41. However, Plaintiffs do not provide any information regarding discussions between Plaintiff-parent and any health care providers at HUP related to breastfeeding and/or using cow's milk-based products in this case. As noted, Plaintiffs plead that Plaintiff-minor ingested formula "on information and belief" only, and similarly plead "on information and belief" that Plaintiff-minor developed NEC as a result.

Plaintiffs also do not explain how cow's milk could be an unreasonably unsafe product. The US FDA regulates both cow's milk and infant formula, and places no restriction on the use of cow's milk-based products for premature infants. FDA's statutory mandate is to prevent the sale of adulterated foods, which are defined as those that may be injurious to human health. 21 U.S.C. §342(a). Far from deeming

² Plaintiffs aver that Abbott sells at least seven types of products directed to preterm and/or low birth weight infants, six of which use the name Similac, and that Mead Johnson sells eight types of infant formulas using the Enfamil brand name. *Id.*, ¶¶ 37-38.

milk injurious, but in order to “promote honesty and fair dealing in the interest of consumers” (21 U.S.C. §341), FDA has created a standard of identity for cow’s milk. See 21 C.F.R. 131.110 (standard of identity for milk.) It has elsewhere said: “First, of all foods, none surpasses milk as a single source of those dietary elements needed for the maintenance of proper health, especially in children and older citizens. For this reason, the USPHS has for many years promoted increased milk consumption...” U.S. Dep’t. of Health and Human Serv. Public Health Serv. FDA, *Grade “A” Pasteurized Milk Ordinance (Grade “A” PMO)*, (2019 Revision), available at <https://www.fda.gov/media/140394/download>.

As for formula, the federal Infant Formula Act of 1980 (“IFA”) was enacted to “assure the safety and nutrition of infant formulas.” Pub. L. No. 96-359, 94 Stat. 1190. The IFA and its implementing regulations outline the requirements that infant formula must meet, including how infant formula is made, its contents and ingredients, and the labels used on its packages, 21 U.S.C. § 350a; 21 C.F.R. §§ 106-07. The IFA provides that infant formulas may only contain “substances that are safe and suitable for use in infant formula.” 21 C.F.R. § 106.40(a). Neither the IFA nor the regulations exclude cow milk as an ingredient, and many infant formulas for sale include cow milk. (Exhibit “A” ¶¶ 37-38); 21 C.F.R § 106.3 (“infant formula” is a “food for infants by reason of its *simulation* of human milk”) (emphasis added). 21 U.S.C. § 350a; 21 C.F.R. §§ 107.50. Before selling any “new infant formula,” a manufacturer must (1) register with the FDA; and (2) submit a notice to the FDA at least 90 days before marketing such formula. The notice must also state that the formula contains the required vitamins and nutrients, as demonstrated by testing. 21 U.S.C. § 350a(b). These same FDA review procedures

apply when a manufacturer makes a “major change” to an existing formula. 21 U.S.C. § 350a(c)(2)(B); 21 C.F.R. § 106.3.

Further, the FDA recognizes that certain infant formulas are intended for low birth weight babies (such as infants born prematurely) or infants with unusual medical or dietary problems. Indeed, such formulas have special review requirements. 21 U.S.C. § 350a(h); 21 C.F.R. § 107.50(b)(3). As with other formulas, the regulations do not exclude cow milk as an ingredient for instant formulas intended for use by an infant with a low birth weight.

In short, since (1) the scientific authorities cited by Plaintiffs do not say that cow’s milk formula *causes* NEC, (2) the Plaintiffs have provided virtually no information about M.E.’s medical or nutritional circumstances (such as the use of mother’s own milk or the availability of donor milk), (3) FDA recognizes cow’s milk and infant formulas as safe, and (4) since Plaintiffs have not even alleged a probability that M.E. received a Mead Johnson product, there is no basis for any claim that the product is unreasonably dangerous and/or should not be given under any circumstances to premature or low birth weight infants.

IV. ARGUMENT

A. DEMURRER FOR FAILURE TO STATE A CLAIM AS TO COUNTS I, II, III, IV & V

Pursuant to Pa.R.C.P. 1028(a)(4), a party may file preliminary objections to a complaint, in the nature of a demurrer, for legal insufficiency in a pleading. A court should grant a demurrer where, accepting as true all well pled facts, a legal cause of action cannot be maintained upon those facts. Pa.R.C.P. 1028(a)(4); *See also, Willet v. Pennsylvania Med. Catastrophe Loss Funds*, 702 A.2d 850, 853 (Pa. 1997). In this

case, Counts I, II, III, IV, and V of Plaintiffs' Complaint should be stricken pursuant to this Rule, as Plaintiffs have failed to plead certain core facts with sufficient detail to survive the pleading stage. For the reasons set forth, *supra*, where Plaintiffs' fail to demonstrate Moving Defendants' cow's milk-based product was unreasonably dangerous, Plaintiffs fail to state a cause of action upon which relief can be granted at Counts I, II, III, IV, and V.

Plaintiffs allege in Counts I and II of the Complaint that Moving Defendants, "as the manufacturers and/or sellers of the products at issue in this litigation" owed Plaintiffs and the public a duty to manufacture, sell, and distribute their products in a manner that was not unreasonably dangerous and to warn of unreasonable risk of harm posed by their products. Counts I and II are based upon Plaintiffs' theory against Moving Defendants that Moving Defendants' cow's milk-based products are unreasonably dangerous, and therefore defective, for strict liability purposes, under claims of design defect and failure-to-warn. In support of this theory, Plaintiffs cite to five studies comparing cow's milk-based products to breast milk, a Surgeon General report on the subject, and a statement by the American Academy of Pediatrics. Taking these facts as pleaded by Plaintiffs as true, Plaintiffs have failed to state a claim for defective design and failed to state a claim for failure-to-warn, due to an absence of proof of that the products are indeed unreasonably dangerous.

"The law governing strict products liability actions in Pennsylvania has been developed based upon the principles outlined in Section 402A of the Second Restatement of Torts." *High v. Pennsy Supply, Inc.*, 154 A.3d 341 (Pa. Super. 2017). Section 402(A) provides:

- (1) One who sells any product in a defective condition unreasonably dangerous to the user or consumer or to his property is subject to liability for physical harm thereby caused to the ultimate user or consumer, or to his property, if
 - (a) the seller is engaged in the business of selling such a product, and
 - (b) it is expected to and does reach the user or consumer without substantial change in the condition in which it is sold.
- (2) The rule stated in Subsection (1) applies although
 - (a) the seller has exercised all possible care in the preparation and sale of his product, and
 - (b) the user or consumer has not bought the product from or entered into any contractual relation with the seller.

Restatement (Second) of Torts § 402(A).

To survive preliminary objections, Plaintiffs must aver sufficient facts, together with the documents and exhibits attached thereto, to make out a *prima facie* case as to all elements of the cause of action. *Northern Forests II, Inc. v. Keta Realty Co.*, 130 A.3d 19, 35 (Pa. Super. 2015).

“The threshold inquiry in all products liability cases is whether there is a defect which rendered the product unreasonably dangerous.” *Weiner v. American Honda Motor Co., Inc.*, 718 A.2d 305, 307 (Pa. Super. 1998). “A product is defective when it is not safe for its intended use, i.e., the product left the supplier's control lacking any element necessary to make it safe for its intended use.” *Id.* at 308. Whether a product is “unreasonably dangerous” is a question of law. *Id.*

Based on the foregoing, Plaintiffs must aver sufficient facts demonstrating the Moving Defendants' products are unreasonably dangerous for their intended use, triggering Moving Defendants' duty to warn. The only factual reference Plaintiffs make with regard to intended use is to marketing campaigns, where Defendant Manufacturers advertised that "cow's milk-based products are necessary for proper growth and development of preterm infants." See Exhibit "A" at ¶ 43. They have not averred sufficient facts to demonstrate that cow's milk-based products are unreasonably dangerous for this purpose, as the studies and reports they cite in their Complaint do not say or support – based on the very allegations in the Complaint – what Plaintiffs claim they do. These studies and reports are the sole factual support that the products in question "cause" NEC, and are the foundation for their strict products liability claims of design defect and failure-to-warn.

At the outset, Plaintiffs appropriately acknowledge that "[p]reterm and low-birth-weight infants are *especially susceptible* to NEC." See Exhibit "A" at ¶ 16 (emphasis added). Following this, Plaintiffs make the core claim of their Complaint – that cow's milk-based feeding products cause NEC in preterm and low birth weight infants – and that "[e]xtensive scientific research, including numerous randomized controlled trials" confirm this claim. *Id.* However, the portions of the research and trials cited by Plaintiffs in their Complaint belie their core claim.

The first study cited by Plaintiffs states, according to the Complaint, that "NEC was six to ten times *more common* in exclusively cow's milk formula-fed babies than in exclusively breast milk-fed babies and three times more common in babies who received a combination of formula and breast milk." *Id.* at ¶ 17 (emphasis added). To

say that NEC is more common in infants fed cow's milk-based products than those fed breast milk is to say that NEC **still occurs in infants fed exclusively breast milk**, but only at a lower rate. Thus, Plaintiffs' first study does not state cow's milk-based products cause NEC. Indeed, the study itself³ explains that the difference in NEC incidence may be mediated by the protective effects of immunoglobulin in breast milk, which, when added to formula, also protected against NEC: "We suggest, in the light of the finding that oral immunoglobulin in formula fed babies was prophylactic, that breast milk may protect against necrotizing enterocolitis by providing IgA in the gut lumen." Lucas, et al., *Breast Milk and Neonatal Necrotizing Enterocolitis*, 336 LANCET 1519, 1522 (1990). The article goes on to *recommend* the concomitant use of bovine formulas to meet the increased nutritional needs of premature infants. *Id.*

As averred in the Complaint, the second study cited by Plaintiffs states that "preterm babies fed an exclusive breast milk-based diet were 90% less likely to develop surgical NEC (NEC that requires surgical treatment), compared to preterm babies fed a diet that included some cow's milk-based products." *Id.* at ¶ 18. To state that preterm infants fed only breast milk are **less likely** to develop a form of NEC is to admit that NEC still develops in preterm infants **regardless of the diet**. Thus, Plaintiffs' second study likewise does not state that cow's milk-based feeding products cause NEC. To the contrary, it too posits that breast milk is simply protective: "These data suggest that

³ For the Court's convenience, Moving Defendants have attached as Exhibit "B" a copy of A. Lucas, et al., *Breast Milk and Neonatal Necrotizing Enterocolitis*, 336 LANCET 1519-1523 (1990), which is the first study that Plaintiffs quote from, and rely on, in their Complaint, but have failed to attach. Where a plaintiff has averred the existence of certain written documents and premised a cause of action upon those documents, it is proper in Pennsylvania for a defendant to attach those documents in support of a demurrer. See *Richardson v. Wetzel*, 74 A.3d 353, 358 n.4 (Pa. Commw. Ct. 2013). As Plaintiffs in the instant matter rely extensively on this and other studies to prove their theory of causation, Moving Defendants have properly attached them here for the Court's consideration.

exclusive human milk diets may exert protective, rather than threshold, effects with respect to NEC.” Sandra Sullivan, et al., *An Exclusively Human Milk-Based Diet is Associated with a Lower Rate of Necrotizing Enterocolitis than a Diet of Human Milk and Bovine Milk-Based Products*, 4 J. PEDIAT. 562, 566 (2010), a true and correct copy of which is attached hereto as Exhibit “C.”

The third study cited by Plaintiffs concluded, per the Complaint, “fortification of breast milk with a cow’s milk-based fortifier resulted in a 4.2-fold increased risk of NEC and a 5.1-fold increased risk of surgical NEC or death, compared to fortification with a breast milk-based fortifier.” *Id.* at ¶ 19. As Plaintiffs admitted in the Complaint, preterm and low-weight-birth infants are especially susceptible to NEC. Put another way, **these infants are already at an increased risk of NEC regardless of their diet.** This study, as described in Plaintiffs’ Complaint, reflects this in explaining different rates of risk of developing NEC when using cow’s milk-based or breast milk-based fortifiers. What the study does not state, as alleged in the Complaint, is that cow’s milk-based fortifiers cause NEC.

The Surgeon General report cited by Plaintiffs is alleged in the Complaint to reiterate the principle made in the prior three studies and states that “formula feeding is associated with *higher rates*” of NEC in preterm infants and that “premature infants who are not breastfed are 138% more likely to develop NEC.” *Id.* at ¶ 20 (emphasis added). If cow’s milk-based formula caused NEC as Plaintiffs aver, one might expect the Surgeon General report to so state. Instead, the Surgeon General report, as described in Plaintiffs’ Complaint at ¶ 20, makes the same acknowledgment as Plaintiffs – that preterm infants are highly susceptible to NEC regardless of their diet, and that NEC

occurs in different rates in preterm infants fed cow's milk-based products and breast milk. The report does not state that the former causes NEC.

According to the Complaint, the American Academy of Pediatrics makes a nearly identical statement to the Surgeon General report. *Id.* at ¶ 21. The Academy makes a recommendation that "all premature infants should be fed either their mother's milk or, if their mother's milk is unavailable, pasteurized donor milk," which recommendation is alleged to be related in part to "lower rates... of NEC." *Id.* This statement acknowledges that NEC still occurs in preterm infants fed only breast milk, but simply at a lower rate. According to the Complaint, the Academy does not state that cow's milk-based feeding products cause NEC. Instead, as quoted by Plaintiffs, the statement touts the "potent protective effects of breastmilk." *Id.*

The fourth and fifth studies cited by Plaintiffs in their Complaint provide similar information. As alleged in the Complaint, a study "found that premature and low-birth-weight infants fed an exclusive breast-milk-based diet suffered NEC only 3% of the time while premature and low-birth-weight infants receiving cow's milk-based formula suffered NEC 21% of the time." In another study, as alleged in the Complaint, "babies given exclusively breast milk products suffered NEC 5% of the time," whereas "babies given cow's milk products suffered NEC 17% of the time." *Id.* at ¶ 22-23. Once again, these studies, based on the allegations in Plaintiffs' Complaint, do not state that cow's milk-based formula causes NEC.

Ultimately, Plaintiffs' claim that Moving Defendants' cow's milk-based feeding products "cause" NEC and are therefore unreasonably dangerous rests upon the notion that correlation equals causation. The numerous studies and reports cited by Plaintiffs

in their Complaint purportedly show higher rates of NEC in preterm and low birth weight infants fed cow's milk-based diets than those fed breast milk, but this data exists in a world where Plaintiffs admit these infants are at a high risk of developing NEC regardless of diet. All that Plaintiffs' Complaint demonstrates, as pleaded under these facts, is that breast milk may be protective against the risk of NEC, not that cow's milk-based alternatives affirmatively cause NEC. This proposition does not make the Moving Defendants' cow's milk-based alternatives unreasonably dangerous within the meaning of § 402(A) of the Restatement (Second) of Torts. Thus, Plaintiffs' Complaint fails to aver sufficient facts to demonstrate that Moving Defendants' products are indeed unreasonably dangerous and maintain a cause of action sounding in strict products liability. Consequently, Plaintiffs' Complaint should be stricken at Counts I, II, III, IV, and V for failure to state a claim.

B. DEMURRER FOR FAILURE TO STATE A CLAIM AS TO COUNTS IV & V

Counts IV and V of Plaintiffs' Complaint allege intentional and negligent misrepresentation, respectively, against Moving Defendants. Plaintiffs cannot maintain misrepresentation claims because they fail to allege that they received any specific representation from Moving Defendants on which they relied. In fact, as they have not even alleged that M.E. received a Mead Johnson product, they cannot claim that misrepresentations by Mead Johnson caused reliance or their purported injury.

The elements of a claim for negligent misrepresentation are: "(1) a misrepresentation of a material fact; (2) made under circumstances in which the misrepresenter ought to have known its falsity; (3) with an intent to induce another to act on it; and (4) which results in injury to a party acting in justifiable reliance on the

misrepresentation.” *Bilt-Rite Contractors v. Architectural Studio*, 866 A.2d 270, 277 (Pa. 2005) (quoting *Bortz v. Noon*, 556 Pa. 489, 729 A.2d 555, 561 (Pa. 1999)). Negligent misrepresentation differs from intentional misrepresentation “in that the misrepresentation must concern a material fact and the speaker need not know his or her words are untrue, but must have failed to make a reasonable investigation of the truth of these words.” *Bortz*, 729 A.2d at 561.

The elements of an intentional misrepresentation claim require: “(1) A representation; (2) which is material to the transaction at hand; (3) made falsely, with knowledge of its falsity or recklessness as to whether it is true or false; (4) with the intent of misleading another into relying on it; (5) justifiable reliance on the misrepresentation; and (6) the resulting injury was proximately caused by the reliance.” *Bortz*, 729 A.2d at 499 (citing *Gibbs v. Ernst*, 647 A.2d 882, 889 (1994), citing, Restatement (Second) of Torts § 525 (1977)).

Here, Plaintiffs’ claims fail to allege that they received any specific representation from Moving Defendants, intentional or otherwise. Plaintiffs further fail to allege that they relied on a specific representation of the Moving Defendants. Because of these omissions from Plaintiffs’ Complaint, Plaintiffs have failed to articulate a viable claim for intentional and negligent misrepresentation. *See, e.g., Cruz v. Roberts*, No. CI-04-01947, 2005 Pa. Dist. & Cnty. Dec. LEXIS 186, 70 Pa. D. & C.4th 225 (Pa. CCP Jan. 26, 2005) (dismissing negligent and intentional misrepresentation claims for insufficient pleading); *see also Kepner v. Tine*, No. 835 EDA 2015, 2015 Pa. Super. Unpub. LEXIS 4257 (Pa. Super. Nov. 25, 2015) (dismissing fraudulent misrepresentation claim for failure to plead a particular misrepresentation).

Thus, Plaintiffs' intentional and negligent misrepresentation claims against Moving Defendants must be dismissed.

C. MOTION TO STRIKE PLAINTIFFS' COMPLAINT FOR INSUFFICIENT SPECIFICITY AS TO THE FACTS AND ALLEGED INJURIES

Pursuant to Pa.R.C.P. 1028(a)(3), a party may file preliminary objections in the nature of a motion to strike for insufficient specificity in a pleading. A plaintiff's Complaint is required to provide a defendant with notice of what the plaintiff's claims are and the grounds upon which they rest, and the Complaint must also formulate the issues by summarizing the facts essential to support the claims. *Alpha Tau Omega Fraternity v. The University of Pennsylvania*, 464 A.2d 1349, 1352 (Pa. Super. 1983) (citations omitted). Pennsylvania Rule of Civil Procedure 1019(a) provides that "the material facts on which a cause of action or defense is based shall be stated in a concise and summary form." Pa.R.C.P. 1019(a). As the Superior Court has noted,

Rule 1019(a) requires fact pleading. The purpose of 1019(a) is to require the pleader to disclose the material facts sufficient to enable the adverse party to prepare his case. **A complaint therefore must do more than give the defendant fair notice of what the plaintiff's claim is and the grounds upon which it rests. It should formulate the issues by fully summarizing the material facts. Material facts are ultimate facts, i.e., those facts essential to support the claim. Evidence from which such facts may be inferred not only need not but should not be alleged. Allegations will withstand challenge under 1019(a) if (1) they contain averments of all of the facts a plaintiff will eventually have to prove in order to recover, and (2) they are sufficiently specific so as to enable defendant to prepare his defense.**

Baker v. Rangos, 324 A.2d 498, 505-506 (Pa. Super. 1974) (citations and internal quotations omitted) (emphasis added).

Further, it is well established that, with regard to the description of injuries sustained by a plaintiff, the Complaint must be stated with sufficient particularity to put the defendant on notice of evidence that may be produced at trial. *Kelly v. Martino*, 99 A.2d 901 (Pa. 1953). **A plaintiff's Complaint must set forth the extent, nature, location and duration of the injuries suffered, and injuries that are permanent should be stated specifically.** *Miller v. Perrige*, 71 Pa. D. & C.2d 476, 479–80 (Pa. Com. Pl. 1975). See, also, *Kopan v. Hawk*, 14 Pa. D. & C.2d 713, 714 (Pa. Com. Pl. 1958) (“A catchall averment of “other injuries” is nothing more than a generalized averment under which any injuries whatever could be proved at the trial. Defendant would have no knowledge in advance of the trial of what they are.”)

Plaintiffs' Complaint is facially deficient with regard to the specificity of the allegations of the relevant facts and injuries at issue in this case.⁴ Plaintiffs' description of the material facts relating to the minor's care and treatment, diagnosis and injuries is limited to four paragraphs, which are utterly insufficient to enable defendants to prepare their defenses. See Exhibit “A,” ¶¶ 11-13. Plaintiffs aver that the minor was born prematurely but do not identify the gestational age at which the child was born or his birth weight. Plaintiffs' allegation that “upon information and belief,” the minor was fed Similac and/or Enfamil shortly after his birth (*Id.* at ¶ 12) does not comply with the fact-pleading requirements of Rule 1019(a), since such allegations do not provide Moving Defendants with appropriate notice of the facts as to whether the minor actually ingested cow's milk-based products. Further, Plaintiffs have failed to identify which of

⁴ Plaintiffs' complaint violates the most basic pleading rules. It is procedurally deficient and bereft of relevant substantive support. Relying upon vague place-holder pleading conventions (e.g., “upon information and belief,” “and/or”) and citation to inapposite scientific studies, Plaintiffs' complaint is replete with supposition, leaps in logic and unsubstantiated innuendo. The Court should not countenance such flouting of the rules.

the numerous products sold by Abbott and Mead Johnson under the Similac and Enfamil brand names were ingested by the minor. *Id.* at ¶¶ 37-38. Plaintiffs' Complaint further fails to provide a description of the material facts as to the period of time in which such products were ingested, when the minor was allegedly diagnosed with NEC and what treatment was provided for that condition.

In short, Plaintiffs' Complaint is inconsistent with the requirements of the Pennsylvania Rules of Civil Procedure as to the necessary specificity for the description of the facts and alleged injuries sustained. The facts in the Complaint are pleaded almost entirely "on information and belief." These omissions are fatal defects in Plaintiff's Complaint. Therefore, Plaintiffs' Complaint should be stricken in its entirety.

D. MOTION TO STRIKE PLAINTIFFS' CLAIMS FOR PUNITIVE DAMAGES

As in the other infant formula cases, In the *Ad Damnum* clauses of Counts I, II, III, IV, and V of the Complaint, Plaintiffs make baseless accusations that Moving Defendants engaged in oppressive, reckless, malicious and/or fraudulent conduct that allegedly justify an award of punitive damages. See Exhibit "A," pp. 22, 25, 28, and 31. However, the Complaint contains no specific allegations of conduct that would permit recovery of punitive damages as to Moving Defendants. Rather, Plaintiffs merely allege that "upon information and belief" M.E. may have been given a cow's milk-based infant formula following birth, absent any context to indicate that such an action was inappropriate based on the specific issues involved in M.E.'s medical care and condition following birth. For example, the Complaint gives no indication of whether Plaintiff-parent refused or was unable to provide breast milk and provides no information as to

discussions between her and any health care providers regarding the purported use of cow's milk-based products.

Plaintiffs' allegations of oppressive, malicious and similar conduct must be rejected as mere boilerplate. As discussed above, the FDA specifically approves the use of infant formula in care of low birth weight infants, with no restriction as to the use of cow's milk-based products for such infants. Indeed, the fact that Plaintiffs have filed numerous lawsuits against at least four other hospitals in Philadelphia based on identical claims belies the contention that Moving Defendants engaged in outrageous or malicious conduct in allegedly feeding the Plaintiff-minor with cow's milk-based infant formula. Absent specific factual allegations to justify the claim that the use of infant formula in M.E.'s case was extreme and outrageous, there is no basis for an award of punitive damages in this case. Merely contending that punitive damages should be awarded with no supporting factual justification requires dismissal of this claim.

Since the purpose of punitive damages is not compensation of a plaintiff but punishment of the defendant and deterrence, punitive damages can be awarded only for conduct involving some element of outrage. *Hutchinson v. Luddy*, 582 Pa. 114, 870 A.2d 766 (2005). For that reason, Pennsylvania Supreme Court decisions establish that "punitive damages are an 'extreme remedy' available in only the most exceptional matters." *Wagner v. Onofrey*, 2006 Pa. Dist. & Cnty. Dec. LEXIS 333, *11 (Pa. Com. Pl. 2006) (citing *Phillips v. Cricket Lighters*, 584 Pa. 179, 188, 883 A.2d 439, 445 (2005)). "In fact, punitive damages are specifically designed to heap an additional punishment on a defendant who is found to have acted in a fashion which is particularly egregious." *Wagner* at *12.

Punitive damages may not be awarded for misconduct that constitutes ordinary negligence such as inadvertence, mistake and errors of judgment. *Martin v. Johns-Manville Corp.*, 494 A.2d 1088, 1097 (Pa. 1985); *McDaniel v. Merck, Sharp & Dohme*, 533 A.2d 436, 437 (Pa. Super. 1987). An award of punitive damages must be supported by evidence of conduct more serious than the mere commission of the underlying tort. *Allstate Ins. Co. v. A.M. Pugh Assoc., Inc.*, 604 F. Supp. 85, 99 (M.D. Pa. 1984).

The Supreme Court has made clear that when assessing the propriety of the imposition of punitive damages, “the state of mind of the actor is vital. The act or failure to act, must be intentional, reckless or malicious.” *Hutchinson, supra* at 770. An appreciation of the risk is a necessary element of the mental state required for the imposition of punitive damages. *Id.* at 772. Thus, “a punitive damages claim must be supported by evidence sufficient to establish that (1) a defendant had a subjective appreciation of the risk of harm to which the plaintiff was exposed and that (2) he acted, or failed to act, as the case may be, in conscious disregard of that risk.” *Id.*

Where the facts as averred show nothing more than negligence, a lapse in judgment, or mere inadvertence, courts in Pennsylvania have dismissed pleas and claims for punitive damages, often at the pleadings stage of litigation and even if the complaint alleged severe injuries or death. See, e.g., *Brownawell v. Bryan*, 40 Pa. D. & C.3d 604, 606 (Pa. Com. Pl. 1985) (dismissing punitive damages claim where a plaintiff alleged that a physician negligently performed a spinal fusion surgery that left the plaintiff with severe neurological defects, and noting that “**the mere pleading of outrageous conduct** does not, of course, satisfy the requirement stating facts which, if proven, would form a basis for a jury concluding that the conduct was such that an

award of punitive damages was warranted.”) (emphasis added); *Wagner, supra* at *11 (contentions that physician failed to prescribe antibiotics, order certain tests or request an infectious disease consult constituted “nothing more than ordinary negligence and are insufficient to support an award of punitive damages.”); *McCardle v. Aldinger*, 5 Pa. D. & C.4th 421, 428 (Pa. Com. Pl. 1996) (sustaining preliminary objections and dismissing claim for punitive damages where the plaintiff alleged negligence in the prenatal care of her child that led to the child was stillborn and holding that “[i]t is not the outcome of the alleged negligence that is of consideration, but rather the alleged conduct of defendants that is at issue.”); *Flurer v. Pocono Medical Ctr.*, 15 Pa. D. & C.4th 645, 670 (Pa. Com. Pl. 1992) (sustaining preliminary objections and finding that plaintiffs were not “capable of pleading the requisite behavior” for an award of punitive damages where a hospital allegedly failed to properly utilize a fetal monitor on a pregnant woman who was involved in a serious car accident and thereafter delivered a stillborn child).

Conversely, punitive damages have been reserved for those situations that are truly egregious and utterly outrageous, and typically involve aggravating or other factors that evince a particularly reckless mind or evil motive. *See, e.g., Medvecz v. Choi*, 569 F.2d 1221, 1227-30 (3rd Cir. 1987) (anesthesiologist who abandoned patient on operating room table and left room for a lunch break without securing a suitable replacement could be liable for punitive damages to patient who suffered irreversible paralysis from anesthesia complication that developed during his absence); *Hoffman v. Memorial Osteopathic Hospital*, 492 A.2d 1382, 386-87 (Pa. Super. 1985) (evidence that emergency room physician allowed Guillain-Barre Syndrome patient suffering from

neurological paralysis to remain crying and immobile on floor for two hours as physician repeatedly stepped over patient was sufficient to support punitive damages claim); *Guernsey v. County Living Personal Care Home, Inc.*, 2006 U.S. Dist. LEXIS 31450, 2006 WL 1412765 (M.D. Pa. 2006) (punitive damages recoverable from nursing home officials who allowed resident to have access to room of 86-year old Alzheimer's patient where he repeatedly raped her, since nursing home was aware of resident's prior criminal convictions for sex registration as a sexual offender under Megan's Law, and his prior instances of grabbing and kissing staff); *Lawrence v. Kunkle*, 75 D. & C. 4th 370 (Pa. Com. Pl. 2005) (patient could maintain punitive damages claim against physician who refused to perform emergency surgery because patient did not have medical insurance even though physician knew that patient would likely suffer permanent neurologic and functional deficits if surgery was delayed).

All of the cases in the paragraph above set forth examples of egregious conduct, completely inapposite to the facts of the instant case. The facts underlying Plaintiffs' bare assertions of reckless, outrageous or similar behavior do not even remotely meet the requisite standard under Pennsylvania law that would permit an award of punitive damages. Without any factual support, the conclusory allegation that Moving Defendants were reckless is insufficiently pled and must be stricken from the Complaint pursuant to Rule 1028(a)(3).

E. MOTION TO STRIKE PLAINTIFF-PARENT'S CLAIMS

Plaintiff-parent seeks to recover damages in her own right and as the parent and natural guardian of M.E. Her claims should be dismissed for the reasons set forth below.

Plaintiffs' Complaint includes allegations in each count against Moving Defendants in which it is averred that Plaintiff-parent "suffered significant emotional distress, loss of income, and/or other harms. Her life has been significantly affected by the Injured Infant's injuries." See Exhibit "A," ¶¶ 74, 82, 91, 101, 111, 125, 138, 146. However, no specific cause of action is asserted as to any damages sought on behalf of Plaintiff-parent, who is not alleged in the Complaint to have suffered any physical injuries as a result of the alleged conduct of Moving Defendants.

Further, even if Plaintiff-parent had properly articulated a cause of action in the Complaint to allow her to recover damages in her own right, the Complaint should be stricken pursuant to Pa.R.C.P. 1020(b), which provides as follows:

If persons join as plaintiffs under Rules 2228, 2229(a) or (e), the complaint shall state the cause of action, any special damage, and the demand for relief of each plaintiff in a separate count, preceded by a heading naming the parties to the causes of action therein set forth.

Accordingly, it is improper for Plaintiffs to plead in a single count their claims on behalf of both the Plaintiff-minor and the Plaintiff-parent, as was done in the instant Complaint. Claims on behalf of each of the Plaintiffs must be set forth in separate counts of the Complaint, specifically identifying the cause of action asserted and relief sought in each count.

Additionally, although the statute of limitations for claims asserted on behalf of minors are tolled until the age of majority, Plaintiff-parent's claims were not similarly tolled and were required to have been brought within two years of the alleged injury. See *Fanscali ex rel. Fanscali v. Univ. Health Center of Pittsburgh*, 563 Pa. 439 (2000); *Hathi v. Krewstown Park Apts*, 561 A.2d 1261 (Pa. Super. 1989); 42 Pa.C.S. § 5524.

Plaintiffs allege that M.E. was born on September 28, 2007, was fed Similac and/or Enfamil cow's milk-based products shortly after his birth at Pennsylvania Hospital, and developed NEC shortly thereafter. See Exhibit "A," ¶¶ 11-13. Thus, because Plaintiffs filed the Complaint at issue on March 24, 2022, Plaintiff-parent's claims herein are clearly time-barred based on the applicable statute of limitations and must be dismissed.

F. MOTION TO STRIKE PLAINTIFFS' COMPLAINT FOR FAILURE TO COMPLY WITH Pa.R.C.P. 1024

Pennsylvania Rule of Civil Procedure 1024(a) requires verification of every pleading containing a factual averment based upon the signer's personal knowledge or information and belief. Rule 1024(c) requires that the verification be made by one or more of the parties filing the pleading. In this case, Plaintiffs' counsel signed the verification for the Complaint, in violation of Rule 1024. See Exhibit "A." Accordingly, the Complaint should be stricken for lack of an appropriate verification.

V. REQUESTED RELIEF

For the foregoing reasons, Defendants Mead Johnson & Company, LLC and Mead Johnson Nutrition Company respectfully request that this Honorable Court sustain their Preliminary Objections and enter the attached Order.

Respectfully submitted,

TUCKER LAW GROUP, LLC

Dated: June 15, 2023

/s/ Kenneth A. Murphy

Kenneth A. Murphy, Esquire
Heather R. Olson, Esquire

WELSH & RECKER, P.C.

/s/ Catherine M. Recker

Catherine M. Recker, Esquire
Amy B. Carver, Esquire
Richard D. Walk, III, Esquire

**Attorneys for Defendants,
Mead Johnson & Company, LLC and
Mead Johnson Nutrition Company**

CERTIFICATE OF SERVICE

I, Kenneth A. Murphy, Esquire, do hereby certify that on this day I caused a true and correct copy of the foregoing Preliminary Objections of Defendants Mead Johnson & Company and Mead Johnson Nutrition Company to Plaintiffs' Complaint, and accompanying Memorandum of Law, to be served via electronic filing, on the following counsel of record, addressed as follows:

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Dated: June 15, 2023

EXHIBIT “A”

Court of Common Pleas of Philadelphia County
Trial Division**Civil Cover Sheet**

For Prothonotary Use Only (Docket Number)

MARCH 2022**002617**

E-Filing Number: 2203055175

PLAINTIFF'S NAME ALICE STILLS		DEFENDANT'S NAME MEAD JOHNSON NUTRITION COMPANY	
PLAINTIFF'S ADDRESS 656 N. CONESTOGA ST. PHILADELPHIA PA 19131		DEFENDANT'S ADDRESS ILLINOIS CORPORATION SERVICE C 801 ADLAI STEVENSON DR. SPRINGFIELD IL 62703	
PLAINTIFF'S NAME M E		DEFENDANT'S NAME THE PA HOSPITAL OF THE UNIVERSITY OF PA HEALTH SYSTEM, ALIAS: PENNSYLVANIA HOSPITAL	
PLAINTIFF'S ADDRESS 656 N. CONESTOGA ST. PHILADELPHIA PA 19131		DEFENDANT'S ADDRESS 3400 CIVIC CENTER BLVD. PHILADELPHIA PA 19104	
PLAINTIFF'S NAME		DEFENDANT'S NAME THE TRUSTEES OF THE UNIVERSITY OF PENNSYLVANIA, ALIAS: PENN MEDICINE	
PLAINTIFF'S ADDRESS		DEFENDANT'S ADDRESS 133 SOUTH 36TH ST. PHILADELPHIA PA 19104	
TOTAL NUMBER OF PLAINTIFFS 2	TOTAL NUMBER OF DEFENDANTS 5	COMMENCEMENT OF ACTION <input checked="" type="checkbox"/> Complaint <input type="checkbox"/> Petition Action <input type="checkbox"/> Notice of Appeal <input type="checkbox"/> Writ of Summons <input type="checkbox"/> Transfer From Other Jurisdictions	
AMOUNT IN CONTROVERSY <input type="checkbox"/> \$50,000.00 or less <input checked="" type="checkbox"/> More than \$50,000.00	COURT PROGRAMS <input type="checkbox"/> Arbitration <input type="checkbox"/> Mass Tort <input type="checkbox"/> Commerce <input type="checkbox"/> Settlement <input checked="" type="checkbox"/> Jury <input type="checkbox"/> Savings Action <input type="checkbox"/> Minor Court Appeal <input type="checkbox"/> Minors <input type="checkbox"/> Non-Jury <input type="checkbox"/> Petition <input type="checkbox"/> Statutory Appeals <input type="checkbox"/> W/D/Survival <input type="checkbox"/> Other:		
CASE TYPE AND CODE 2P - PRODUCT LIABILITY			
STATUTORY BASIS FOR CAUSE OF ACTION			
RELATED PENDING CASES (LIST BY CASE CAPTION AND DOCKET NUMBER)		<div style="text-align: center;"> FILED PROTHONOTARY MAR 24 2022 S. RICE </div>	
		IS CASE SUBJECT TO COORDINATION ORDER? YES NO	
TO THE PROTHONOTARY: Kindly enter my appearance on behalf of Plaintiff/Petitioner/Appellant: <u>ALICE STILLS , M E</u> Papers may be served at the address set forth below.			
NAME OF PLAINTIFF'S/PETITIONER'S/APPELLANT'S ATTORNEY TRACY A. FINKEN		ADDRESS ONE LOGAN SQUARE 130 N. 18TH ST. SUITE 1600 PHILADELPHIA PA 19103	
PHONE NUMBER (215) 735-0773	FAX NUMBER (215) 875-7731		
SUPREME COURT IDENTIFICATION NO. 82258		E-MAIL ADDRESS tfinken@anapolweiss.com	
SIGNATURE OF FILING ATTORNEY OR PARTY TRACY FINKEN		DATE SUBMITTED Thursday, March 24, 2022, 04:41 pm	

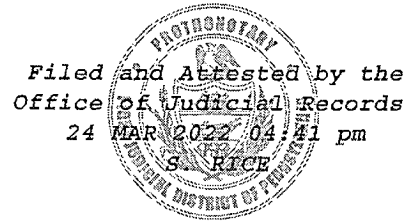
FINAL COPY (Approved by the Prothonotary Clerk)

Case ID: 220302617
Control No.: 23063376

COMPLETE LIST OF DEFENDANTS:

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4. ABBOTT LABORATORIES
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ALICE STILLS, on her own behalf and as
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 a Minor
 656 N. Conestoga Street
 Philadelphia, PA 19131
 Plaintiffs

v.

MEAD JOHNSON & COMPANY, LLC
 Illinois Corporation Service Co.
 801 Adlai Stevenson Drive
 Springfield, IL 62703

MEAD JOHNSON NUTRITION COMPANY
 Illinois Corporation Service Co.
 801 Adlai Stevenson Drive
 Springfield, IL 62703

ABBOTT LABORATORIES
 CT Corporation System
 208 So. Lasalle Street, Suite 814
 Chicago, IL 60604

COURT OF COMMON PLEAS
 PHILADELPHIA COUNTY

CIVIL ACTION

NO.

THE PENNSYLVANIA HOSPITAL OF
THE UNIVERSITY OF PENNSYLVANIA
HEALTH SYSTEM d/b/a PENNSYLVANIA
HOSPITAL

3400 Civic Center Blvd.
Philadelphia, PA 19104

THE TRUSTEES OF THE UNIVERSITY OF
PENNSYLVANIA d/b/a PENN MEDICINE

133 South 36th Street
Philadelphia, PA 19104

Defendants

JURY TRIAL DEMANDED

COMPLAINT IN CIVIL ACTION

NOTICE TO DEFEND

NOTICE

You have been sued in court. If you wish to defend against the claims set forth in the following pages, you must take action within twenty (20) days after this complaint and notice are served, by entering a written appearance personally or by attorney and filing in writing with the court your defenses or objections to the claims set forth against you by the court without further notice for any money claimed in the complaint or for any other claim or relief requested by the plaintiff. You may lose money or property or other rights important to you.

YOU SHOULD TAKE THIS PAPER TO YOUR LAWYER AT ONCE. IF YOU DO NOT HAVE A LAWYER OR CANNOT AFFORD ONE, GO TO OR TELEPHONE THE OFFICE SET FORTH BELOW TO FIND OUT WHERE YOU CAN GET LEGAL HELP.

PHILADELPHIA BAR ASSOCIATION
LAWYER REFERRAL AND INFORMATION SERVICE
ONE READING CENTER
PHILADELPHIA, PA 19107
TELEPHONE: (215) 238-1701

AVISO

Le han demandado a usted en la corte. Si usted quiere defenderse de estas demandas expuestas las páginas siguientes, usted tiene veinte (20) días de plazo al partir de la fecha de la demanda y la notificación. Hace falta asentar una comparencia escrita o en persona o con un abogado y entregar a la corte en forma escrita sus defensas o sus objeciones a las demandas en contra de su persona. Sea avisado que si usted no se defiende, la corte tomará medidas y puede continuar la demanda en contra suya sin previo aviso o notificación. Además, la corte puede decidir a favor del demandante y requiere que usted cumpla con todas las provisiones de esta demanda. Usted puede perder dinero o sus propiedades u otros derechos importantes para usted.

LLEVE ESTA DEMANDA A UN ABOGADO INMEDIATAMENTE. SI NO TIENE ABOGADO O SI NO TIENE EL DINERO SUFICIENTE DE PAGAR TAL SERVICIO, VAYA EN PERSONA O LLAME POR TELEFONO A LA OFICINA CUYA DIRECCION SE ENCUENTRA ESCRITA ABAJO PARA AVERIGUAR DONDE SE PUEDE CONSEGUIR ASISTENCIA LEGAL.

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ATTORNEY FOR PLAINTIFFS

ALICE STILLS, ON HER OWN BEHALF
AND AS PARENT AND NATURAL GUARDIAN
OF M.E., A MINOR
656 N. CONESTOGA STREET
PHILADELPHIA, PA 19131
PLAINTIFFS

v.

MEAD JOHNSON & COMPANY, LLC
ILLINOIS CORPORATION SERVICE Co.
801 ADLAI STEVENSON DRIVE
SPRINGFIELD, IL 62703

MEAD JOHNSON NUTRITION COMPANY
ILLINOIS CORPORATION SERVICE Co.
801 ADLAI STEVENSON DRIVE
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ABBOTT LABORATORIES
CT CORPORATION SYSTEM
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THE PENNSYLVANIA HOSPITAL OF
THE UNIVERSITY OF PENNSYLVANIA
HEALTH SYSTEM D/B/A PENNSYLVANIA

COURT OF COMMON PLEAS
PHILADELPHIA COUNTY

CIVIL ACTION

NO.

the Injured Infant was seriously injured, resulting in long term health effects and accompanying harm to their parent (“the Plaintiff Parent”).

2. Plaintiff brings these causes of action against Defendants to recover for injuries that are the direct and proximate result of the Injured Infant’s consumption of the Defendant Manufacturers’ unreasonably dangerous cow’s milk-based infant feeding products, which were acquired and supplied without adequate warning to the Injured Infant at Pennsylvania Hospital, owned and operated by Penn Medicine.

II. PARTIES

3. Plaintiff Alice Stills is a natural adult person and a resident of Pennsylvania. Ms. Stills is the parent and natural guardian of M.E., a minor. Ms. Stills’ address is 656 N Conestoga Street, Philadelphia, Pennsylvania 19131.

4. Defendant Mead Johnson Nutrition Company is a corporation, incorporated under the laws of the State of Delaware. Its principal place of business is Illinois. Defendant Mead Johnson & Company, LLC, is a limited liability company, organized under the laws of the State of Delaware. Its citizenship is that of its sole member, Mead Johnson Nutrition Company. Defendants Mead Johnson Nutrition Company and Mead Johnson & Company, LLC, (together, “Mead”) are manufacturers of cow’s milk-based infant feeding products and market many of these products under the “Enfamil” brand name.

5. Defendant Abbott Laboratories (“Abbott”) is a corporation, incorporated under the laws of the State of Illinois. Its principal place of business is in Illinois. Abbott is a manufacturer of cow’s milk-based infant feeding products and markets many of its products under the “Similac” brand name.

6. Defendant The Pennsylvania Hospital of the University of Pennsylvania Health System d/b/a Pennsylvania Hospital is a non-profit corporation incorporated and registered to do business under the laws of the Commonwealth of Pennsylvania. Its principal place of business is Philadelphia, Pennsylvania. Pennsylvania Hospital is a registered name of The Pennsylvania Hospital of the University of Pennsylvania Health System. The sole member of The Pennsylvania Hospital of the University of Pennsylvania Health System is The Trustees of the University of Pennsylvania.

7. Defendant The Trustees of the University of Pennsylvania d/b/a Penn Medicine is a non-profit corporation registered to do business in the Commonwealth of Pennsylvania. Its principal place of business is Philadelphia, Pennsylvania. Penn Medicine is a registered name of The Trustees of the University of Pennsylvania.

III. JURISDICTION AND VENUE

8. This Court has jurisdiction in this matter pursuant to 42 Pa. C.S.A. § 931. Defendants conduct authorized business in the Commonwealth of Pennsylvania. They have sufficient minimum contacts with and purposefully avail themselves of the markets of this Commonwealth. This suit arises out of Defendants' forum-related activities, such that the Court of Common Pleas of Philadelphia County's exercise of jurisdiction would be consistent with traditional notions of fair play and substantial justice.

9. Venue is proper in the Court of Common Pleas of Philadelphia County pursuant to Rules 1006(b), 1006(c)(1), and 2179(a) of the Pennsylvania Rules of Civil Procedure because Defendants are corporations or similar entities that regularly conduct business in Philadelphia County, which is also the county where Plaintiff's causes of action arose, and the county where the occurrences took place out of which Plaintiff's causes of action arose.

10. This action is not subject to the Compulsory Arbitration Program of the Court of Common Pleas of Philadelphia County because the amount in controversy, excluding interest and costs, is in excess of \$50,000.

IV. FACTUAL ALLEGATIONS

M.E.'s NEC Diagnosis

11. M.E. was born prematurely at Pennsylvania Hospital in Philadelphia, Pennsylvania on September 28, 2007.

12. Upon information and belief M.E. was fed Similac and/or Enfamil cow's milk-based products by staff at Pennsylvania Hospital from shortly after his birth.

13. Upon information and belief shortly after M.E. first ingested the Defendant Manufacturers' products, he developed NEC.

Cow's Milk-Based Feeding Products Are Known to Cause NEC

14. NEC is a devastating disease that is the most frequent and lethal gastrointestinal disorder affecting preterm infants. NEC develops when harmful bacteria breach the walls of the intestine, causing portions of the intestine to become inflamed and often to die. Once NEC develops, the condition can progress rapidly from mild feeding intolerance to systemic and fatal sepsis. Up to 30 percent of NEC-diagnosed infants die from the disease.

15. Preterm and low-birth-weight infants are especially susceptible to NEC because of their underdeveloped digestive systems. Extensive scientific research, including numerous randomized controlled trials, has confirmed that cow's milk-based feeding products cause NEC in preterm and low-birth-weight infants, which in turn may lead to other medical complications, surgeries, long-term health problems, and death.

16. For example, in one randomized, multicenter study of 926 preterm infants, NEC was six to ten times more common in exclusively cow's milk formula-fed babies than in exclusively breast milk-fed babies and three times more common in babies who received a combination of formula and breast milk. For babies born at more than 30 weeks gestation, NEC was 20 times more common in those only fed cow's milk formula than in those fed breast milk.

17. Another randomized controlled trial showed that preterm babies fed an exclusive breast milk-based diet were 90% less likely to develop surgical NEC (NEC that requires surgical treatment), compared to preterm babies fed a diet that included some cow's milk-based products.

18. Yet another study that analyzed the data from a 12-center randomized trial concluded that fortification of breast milk with a cow's milk-based fortifier resulted in a 4.2-fold increased risk of NEC and a 5.1-fold increased risk of surgical NEC or death, compared to fortification with a breast milk-based fortifier.

19. A Surgeon General report, The Surgeon General's Call to Action to Support Breastfeeding, warns that, "for vulnerable premature infants, formula feeding is associated with higher rates of necrotizing enterocolitis." The report also states that premature infants who are not breastfed are 138% more likely to develop NEC.

20. The American Academy of Pediatrics, "an organization of 67,000 pediatricians committed to the optimal physical, mental, and social health and well-being for all infants, children, adolescents, and young adults," has advised that all premature infants should be fed either their mother's milk or, if their mother's milk is unavailable, pasteurized human donor milk. This recommendation is based on the "potent benefits of human milk," including "lower rates of . . . NEC."

21. A multicenter, randomized, controlled trial found that premature and low-birth-weight infants fed an exclusive breast milk-based diet suffered NEC only 3% of the time while premature and low-birth-weight infants receiving cow's milk-based formula suffered NEC 21% of the time.

22. Another study conducted a randomized comparison of extremely preterm infants who were given either (a) a diet of breast milk fortified with a breast milk-based fortifier or (b) a diet containing variable amounts of cow's milk-based products. The babies given exclusively breast milk products suffered NEC 5% of the time. The babies given cow's milk products suffered NEC 17% of the time.

Safer, Nutritionally Superior Alternatives To Cow's Milk-Based Products Exist

23. A range of options are available that allow preterm and low-birth-weight infants to be fed exclusively human milk-based nutrition. For example, in addition to the mother's own milk, an established network delivers pasteurized donor breast milk to hospitals nationwide. Moreover, hospitals have access to shelf-stable formula and fortifiers derived from pasteurized breast milk.

24. A diet based exclusively on breast milk and breast milk fortifiers provides all the nutrition necessary to support premature and low-birth-weight infants without the elevated risk of NEC associated with cow's milk-based products. For example, in a study analyzing preterm infants who were fed an exclusive breast milk-based diet until they reached 34 weeks, all 104 infants exceeded standard growth targets and met length and head-circumference growth targets, demonstrating that infants can achieve and mostly exceed targeted growth standards when receiving an exclusive breast milk-based diet. This is particularly true given the ability of breast milk-based fortifiers to provide the additional nutritional supplements necessary for adequate growth while receiving the protective benefits of a breast milk diet.

25. The Defendant Manufacturers' products not only pose a threat to infants' health, but also displace the breast milk they could otherwise receive. This displacement only increases infants' vulnerability to NEC, as studies show that breast milk protects against the disease. For example, a study analyzing 1,587 infants across multiple institutions concluded that an exclusive breast milk-based diet is associated with significant benefits for extremely premature infants and that it produced no feeding-related adverse outcomes.

26. For the above reasons, experts acknowledge that breast milk is the best source of nutrition for preterm infants and those at risk for NEC. Breast milk-based nutrition nourishes infants while creating a significantly lower risk of NEC.

27. At the time the Injured Infant was fed the Defendant Manufacturers' products, the science clearly demonstrated to Defendants that these products cause NEC and greatly increase the likelihood that a baby will develop NEC, leading to severe injury and often death.

28. Despite the scientific consensus that the Defendant Manufacturers' cow's milk-based products present a dire threat to the health and development of preterm infants, the Defendant Manufacturers have made no changes to their products or the products' packaging, guidelines, instructions, or warnings. Instead, they have continued to sell their unreasonably dangerous products. In addition, they incentivize hospitals that know the risks to use their products by providing them to the hospital for free or at a significant discount, in order that vulnerable infants and their families will become accustomed to using their products before discharge.

***The Defendant Manufacturers' False And Misleading Marketing
Regarding Cow's Milk-Based Infant Products***

29. Abbott and Mead have aggressively marketed their cow's milk-based products as medically endorsed and nutritionally equivalent alternatives to breast milk, including prior to the Injured Infant's birth.

30. Abbott's and Mead's marketing approach includes targeting the parents of preterm infants while they are still in the hospital with messages that the Defendant Manufacturers' cow's milk formulas and fortifiers are necessary for the growth and development of their vulnerable children. Often these tactics implicitly discourage mothers from breastfeeding, which reduces the mother's supply of breast milk. None of the Defendant Manufacturers' marketing materials, including their promotional websites, reference the science showing how significantly their products increase the risk of NEC.

31. Numerous studies have shown the detrimental impact of formula advertising on the rates of initiation and continuation of breastfeeding, including studies that show that as "hand feeding" (non-breastfeeding) advertisements increase, reported breastfeeding rates decrease in the following year.

32. Undoubtedly aware of the impact of their advertising, the Defendant Manufacturers, along with other formula manufacturers, are willing to spend massive sums to disseminate their message, with one study estimating that formula manufacturers collectively spent \$4.48 billion on marketing and promotion in 2014 alone.

33. Recognizing the abuse and dangers of infant formula marketing, in 1981, the World Health Assembly—the decision-making body of the World Health Organization—developed the International Code of Marketing of Breast-milk Substitutes ("the Code"), which required companies to acknowledge the superiority of breast milk, the negative effect on breastfeeding of introducing partial bottle-feeding, and the difficulty of reversing the decision not to breastfeed. The Code also forbade advertising or other forms of promotion of formula to the general public, as well as providing sample products to mothers or members of their families.

34. While Abbott and Mead acknowledge the Code on their websites and claim to support the effort to encourage mothers to breastfeed for as long as possible, this is little more than lip service. Instead, the Defendant Manufacturers' aggressive marketing exploits new parents' darkest fears—that the nutrition they are supplying to their child will not provide the best chance of survival—while wholly failing to warn that their products come with a significantly increased risk of NEC.

35. For example, Abbott's website, on a page titled "Infant Formula Marketing," states: "We agree with the World Health Organization that breastfeeding provides the best nutrition for babies, and we support its goal to increase breastfeeding. We also recognize that for infants who aren't breastfed—for medical reasons or otherwise—infant formula is the only appropriate, safe alternative to meet babies' nutritional needs." This statement ignores the existence of donor milk, as well as human milk-based formula.

36. Abbott markets and sells multiple products specifically targeting preterm and low-birth-weight infants, including Liquid Protein Fortifier, Similac NeoSure, Similac Human Milk Fortifiers, Similac Special Care 20, Similac Special Care 24, Similac Special Care 24 High Protein, and Similac Special Care 30. In advertising these products, Abbott emphasizes the products' purported ability to assist underdeveloped babies in reaching their growth targets. For example, on the since-edited webpage regarding Similac NeoSure, Abbott noted: "Your premature baby didn't get her full 9 months in the womb, so her body is working hard to catch up. During her first full year, feed her Similac NeoSure, a nutrient-enriched formula for babies who were born prematurely, and help support her development." Yet, no mention was made of the accompanying significantly increased risk of NEC. At some point, the website was edited to remove this statement. However, upon information and belief, the statement remained on the website until at least December 2020.

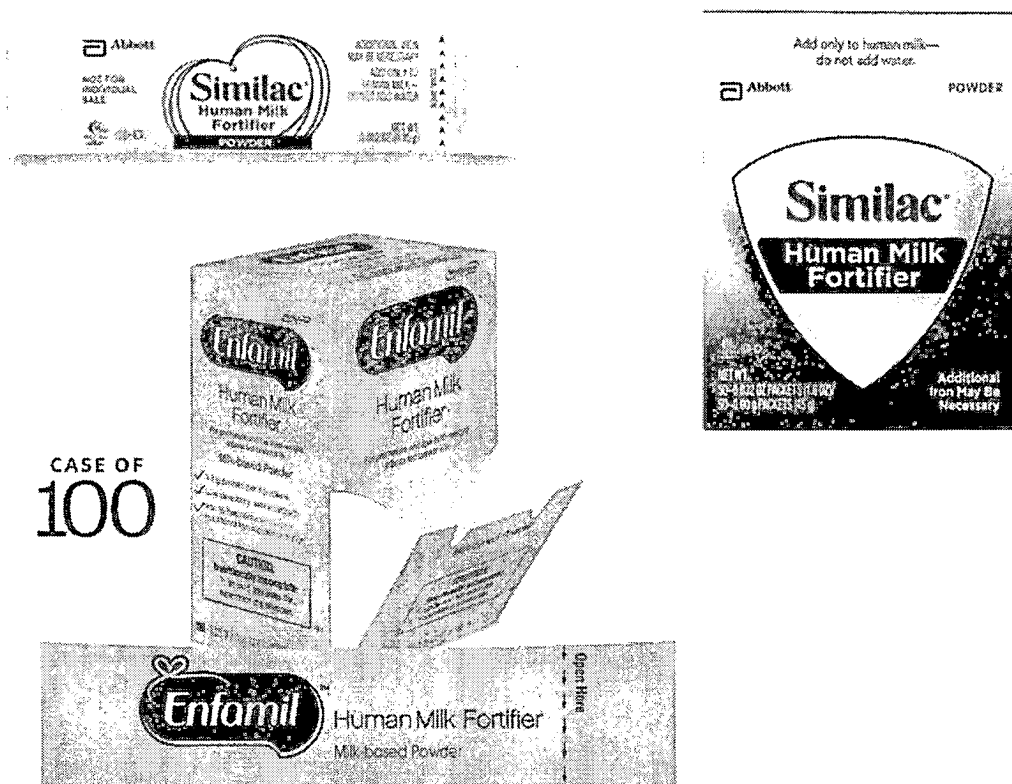
37. Mead markets and sells multiple products specifically targeting premature infants, including Enfamil NeuroPro EnfaCare Infant Formula, Enfamil Premature Infant Formula 24 Cal High Protein, Enfamil Premature Infant Formula 30 Cal with Iron, Enfamil Premature Infant Formula 24 Cal with Iron, Enfamil Premature Infant Formula 20 Cal with Iron, Enfamil 24 Cal Infant Formula, and Enfamil Human Milk Fortifier (acidified liquid and powder). In advertising these products, Mead emphasizes the purported similarities between its formula and breast milk, while failing to include any information about the nutritional deficits and dangers that accompany formula use. For example, the since-edited webpage for Enfamil Enfacare stated: “Premature babies fed Enfamil® formulas during the first year have achieved catch-up growth similar to that of full term, breastfed infants” and noted that Enfamil formulas include “expert-recommended levels of DHA and ARA (important fatty acids found naturally in breast milk) to support brain and eye development.”

38. One Enfamil advertisement, introducing a new product line called Enfamil NeuroPro, is entirely focused on favorably comparing Enfamil’s formula to breast milk, without any mention of the product’s extreme risks. Indeed, the terms “human milk” and “breast milk” are used 13 times in the advertisement, including in such statements as “for decades human milk has inspired the advancements in Enfamil formulas and now through extensive global research, we are taking an even closer look at human milk” and “only Enfamil NeuroPro has a fat blend of MFGM and DHA previously found only in breast milk.” The webpage for the product has made similar manipulative claims, stating “Enfamil is backed by decades of breast milk research and multiple clinical studies” and it claims that “to create our best formulas, we collaborated on some of the most extensive breast milk studies to date[.]”

39. Formula manufacturers have long used their relationships with hospitals and the discharge process to encourage parents to substitute formula for breast milk. They offer free or reduced-cost formula to hospitals for use with infants before discharge. And they offer free formula, coupons, and even entire gift baskets to parents before their infants' discharge from the NICU or hospital.

40. Through this early targeting, the Defendant Manufacturers create brand loyalty under the guise of a "medical blessing," in hopes that new parents continue to use formula after they leave the hospital, resulting in increased expense for parents, significantly increased risk for babies, and increased profit for the Defendant Manufacturers. The Defendant Manufacturers' giveaways and gift baskets send confusing signals to mothers who are simultaneously being encouraged to breastfeed by their healthcare professionals, and they have been shown to negatively impact breastfeeding rates.

41. Further, when the Defendant Manufacturers recognized a shift in the medical community towards an exclusive breast milk-based diet for premature infants, Abbott developed a product called "Similac Human Milk Fortifier," and Mead developed "Enfamil Human Milk Fortifier." These names are misleading in that they suggest that the products are derived from breast milk, when, in fact, they are cow's milk-based products. One study, for example, found that only 8.8 percent of parents surveyed in the NICU interpreted "human milk fortifier" as potentially meaning a cow's milk-based product. The packaging appears as:



42. The Defendant Manufacturers have designed powerful misleading marketing campaigns to deceive parents into believing that: (1) cow's milk-based products are safe, including for preterm infants; (2) cow's milk-based products are equal, or even superior, substitutes to breast milk; (3) cow's milk-based products are necessary for proper growth and development of preterm infants; and (4) physicians consider the Defendant Manufacturers' cow's milk-based products to be a first choice. This marketing scheme is employed despite all Defendants knowing of and failing to warn of the extreme risk of NEC and death that cow's milk-based products pose to preterm infants like the Injured Infant.

The Defendant Manufacturers' Inadequate Warnings

43. Although Mead promotes an aggressive marketing campaign designed to convince parents that its cow's milk-based products are safe and necessary for the growth of a premature infant, the product is in fact extremely dangerous for premature infants. Enfamil products significantly increase the chances of a premature infant developing potentially fatal NEC.

44. The Enfamil products Mead markets specifically for premature infants are commercially available at retail locations and online. No prescription is necessary.

45. Despite knowing of the risk of NEC, the packaging of Mead's products does not warn of the significantly increased risk of NEC (and resulting medical conditions, and/or death) associated with Mead's products, or of the magnitude of this increased risk. Mead likewise did not provide instructions or guidance for how to avoid NEC.

46. Mead cites no medical literature or research to guide the use of its products.

47. Despite knowing of the risk of NEC, Mead did not warn of the significantly increased risk of NEC (and resulting medical conditions, and/or death) associated with its products, or of the magnitude of this increased risk. Mead likewise did not provide instructions or guidance for how to avoid NEC.

48. Mead deceived the public, parents, physicians, other medical professionals, and medical staff into believing that Enfamil products were a safe and necessary alternative, supplement and/or substitute to breast milk.

49. Despite knowing that its products were being fed to premature infants, often without the parents' informed consent, Mead failed to require or recommend that medical professionals inform parents of the significant risk of NEC or to require that parental consent be obtained prior to the products being fed to their babies.

50. Like Mead, Abbott promotes an aggressive marketing campaign designed to make parents believe that its products are safe and necessary for the growth of premature infants, despite the products in fact being extremely dangerous for premature infants. Abbott's products significantly increase the chances of a premature infant getting potentially fatal NEC.

51. The products Abbott markets specifically for premature infants are available at retail locations and online. No prescription is necessary.

52. Despite knowing of the risk of NEC, Abbott did not warn of the significantly increased risk of NEC (and resulting medical conditions, and/or death) associated with its products, or of the magnitude of this increased risk. Abbott likewise did not provide instructions or guidance for how to avoid NEC.

53. Abbott deceived the public, parents, physicians, other medical professionals, and medical staff into believing that its products were a safe and necessary alternative, supplement and/or substitute to breast milk.

54. Despite knowing that its products were being fed to premature infants, often without the parents' informed consent, Abbott failed to require or recommend that medical professionals inform parents of the significant risk of NEC or to require that parental consent be obtained prior to the products being fed to their babies.

Penn Medicine's Failure to Warn

55. On information and belief, Penn Medicine, which operates Pennsylvania Hospital, was aware of the significantly increased risk of NEC and death associated with providing Abbott's and Mead's cow's milk-based products to its premature infant patients. It knew or should have known that feeding these cow's milk-based products can cause NEC in premature infants who otherwise would not have developed this devastating condition. However, instead of warning of those

dangers, or supplying breast milk-based feeding products to preterm infants like the Injured Infant, Penn Medicine has continued to source, distribute, and supply the Defendant Manufacturers' products in its hospitals without any adequate warning.

56. To that end, Penn Medicine has participated in studies designed to increase the use of donor milk while, at the same time, reducing formula feeding in neonates. The University of Pennsylvania School of Nursing, an affiliate of Penn Medicine, has conducted extensive research into the risks associated with feeding formula to premature infants. It recently partnered with the National Institute of Nursing Research to publish clinical determinations based on its experience "changing hospital systems and influencing policy," and its findings were unequivocal:

This is what we know about the science of human milk: it reduces the risk of necrotizing enterocolitis, reduces the risk of infection, [and] creates greater enteral feed tolerance and more rapid weaning from intravenous nutrition. . . .

Other Penn Medicine research has similarly concluded that "[h]uman milk decreases the incidence and severity of . . . necrotizing enterocolitis (NEC)."

57. Penn Medicine also purports to adhere to the tenets of the "Baby Friendly Hospital Initiative," which seeks to increase rates of breastfeeding initiation, exclusivity, and diet duration. The "Baby Friendly Hospital Initiative" specifically targets a reduction in the rates of NEC in preterm infants by encouraging implementation of exclusive breast milk diets among new mothers. Although Pennsylvania Hospital has maintained its "Baby Friendly" designation for years, it has not eliminated or restricted the use of formula or fortifier for preterm infants in its hospitals.

58. Finally, medical providers and staff at Penn Medicine have acknowledged the risks associated with providing the Defendant Manufacturers' cow's milk-based products to premature infant patients instead of breast milk-based nutrition. In an internal newsletter from 2012 touting donor milk programs, Penn Medicine acknowledged the benefits of a human milk-based diet, quoting a staff lactation consultant:

Donor milk is not inexpensive. It costs about \$4.25 per ounce, but the return on investment is huge. “Preemies given mother’s milk get discharged three to four days sooner and also have a six to 10 times lower risk of getting a gastrointestinal complication called necrotizing enterocolitis,” Carpenter said, adding that the infection can cost up to \$250,000 to treat. The average cost to provide a preemie with donor milk: \$125.

59. These statements demonstrate that Penn Medicine knew or should have known of the high increased risk of NEC for premature infants posed by the Defendant Manufacturers’ products.

60. Although Penn Medicine knew or should have known of the serious danger of the Defendant Manufacturers’ products, it has continued to purchase, supply, and distribute these products to preterm infants without providing full and adequate warnings of the attendant risks to parents, healthcare professionals, and other medical staff at its relevant facilities. As a result, the Injured Infant was fed the Defendant Manufacturers’ cow’s milk-based products at Pennsylvania Hospital, causing their injuries. This occurred even though hospitals across the country, including Pennsylvania Hospital, warn and obtain consent from parents before providing other safer forms of nutrition, such as donor breast milk.

61. Penn Medicine’s failure to warn of the risks posed by the Defendant Manufacturers’ products is entrenched (and compounded) by the financial benefits it accrues from its relationships with the Defendant Manufacturers. On information and belief, it has received the Defendant Manufacturers’ cow’s milk-based products for free or at a significant discount, and has granted their sales representatives access to its healthcare professionals and medical staff. These sales representatives have provided deceptive information that Penn Medicine reasonably knew or should have known would ultimately reach parents through those staff. This arrangement dovetails with the Defendant Manufacturers’ own marketing strategy, which aims to “sell and service” healthcare professionals and medical staff as a means of converting them into “extra salespersons.”

Safer Alternative Designs

62. The Defendant Manufacturers' cow's milk-based products made specifically for premature infants are unreasonably unsafe for those infants. The Defendant Manufacturers could have used pasteurized breast milk instead of cow's milk in their products, which would have produced a safer product.

63. Prolacta Bioscience manufactures and sells breast milk-based feeding products, specifically designed for preterm infants, which contain no cow's milk. This alternative design provides all the necessary nutrition for growth and development that cow's milk-based products provide, without the same unreasonably dangerous and deadly effects.

64. On information and belief, Abbott and Mead were aware of the significantly increased risk of NEC and death associated with their cow's milk-based products, and instead of warning of the dangers, or removing them altogether, Abbott and Mead have continued to use cow's milk as the foundation of their products.

CAUSES OF ACTION
COUNT I: STRICT LIABILITY FOR DESIGN DEFECT
(Against Abbott and Mead)

65. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.

66. Abbott and Mead, as the manufacturers and/or sellers of the products at issue in this litigation, owed a duty to the consuming public in general, and the Plaintiff Parent in particular, to manufacture, sell, and distribute their products in a manner that was not unreasonably dangerous.

67. Abbott and Mead also owed a duty to the consuming public in general, and the Plaintiff Parent in particular, to manufacture, sell, and distribute their products in a manner that was merchantable and reasonably suited for their intended use.

68. Abbott and Mead knew that their products would be used to feed premature infants like the Injured Infant and knew (or reasonably should have known) that use of their cow's milk-based products significantly increased the risk of NEC, serious injury, and death, and that such use was therefore unreasonably dangerous to premature infants, not reasonably suited for the use intended, not merchantable, and had risks that exceeded a reasonable buyer's expectations. Nonetheless, they continued to sell and market their defective products as appropriate for premature infants.

69. The Injured Infant ingested Abbott and/or Mead's unreasonably dangerous cow's milk-based products. The risks of feeding those products to the Injured Infant outweighed the benefits. An ordinary consumer would not expect those products to carry a significant risk of serious injury and death from NEC.

70. Abbott and Mead knew (or reasonably should have known) that breast milk-based nutrition did not carry the same risks of NEC, serious injury, and death that their products do.

71. Abbott's and Mead's products contained cow's milk at the time they left the manufacturing facility.

72. Abbott and Mead did not develop a human-milk based product that was safer for premature infants and did not reformulate their products to reduce the risk of NEC, serious injury, and death, even though doing so was economically and technologically feasible and even though pasteurized breast milk was an available alternative.

73. Abbott's and/or Mead's products were fed to the Injured Infant, which caused and/or increased the risk of their NEC and injuries.

74. As a further direct result, the Plaintiff Parent suffered significant emotional distress, loss of income, and/or other harms. Her life has been significantly affected by the Injured Infant's injuries.

WHEREFORE, Plaintiff demands judgment against the Defendant Manufacturers as follows:

- a. For compensatory damages in an amount to be proven at trial and in excess of \$50,000 and this Court's arbitrational limit;
- b. For damages for past, present, and future emotional distress, loss of enjoyment of life, pain and suffering, mental anguish, and other non-economic losses sustained as a result of the Defendants Manufacturers' conduct;
- c. For past, present, and future out-of-pocket costs, lost income and/or lost revenue, and/or lost profits, and/or lost business opportunity, lost earning capacity, and costs related to medical or mental health treatment which have or may be recommended;
- d. For punitive damages in excess of \$50,000 and this Court's arbitrational limit resulting from the Defendant Manufacturers' oppressive, fraudulent, and/or malicious conduct, as permitted by law;
- e. For interest as permitted by law;
- f. For attorney's fees, expenses, and recoverable costs incurred in connection with this action; and
- g. For such other and further relief as the Court deems proper.

**COUNT II: STRICT LIABILITY FOR FAILURE TO WARN
(Against Abbott and Mead)**

75. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.

76. Abbott and Mead, as the manufacturers and/or sellers of the infant products at issue in this litigation, owed a duty to the consuming public in general, and the Plaintiff Parent in particular, to provide adequate warnings or instructions about the dangers and risks associated with the use of

their products with preterm infants, specifically including but not limited to the risk of NEC, serious injury, and death.

77. Abbott's and Mead's duty to warn is part of their general duty to design, manufacture, and sell their infant products in a manner that is reasonably safe for their foreseeable uses. By designing their products with cow's milk-based ingredients, Abbott and Mead undertook a duty to warn of the unreasonable risk of harm posed by those ingredients, specifically including the significantly increased risk of NEC, severe injury, and death. The failure to warn makes the products at issue in this litigation unreasonably dangerous.

78. Specifically, Abbott and Mead breached their duty to warn of the foreseeable risks of the infant products at issue in this litigation because they knew or should have known that their cow's milk-based premature infant products would be fed to premature infants like the Injured Infant, and that their products might cause the Injured Infant to develop NEC, severe injury, or death, yet they failed to provide adequate warnings of those risks. Among other risks, the Defendant Manufacturers:

- a. Failed to warn that cow's milk-based products significantly increase the risk of NEC, severe injury, and death for the Injured Infant; and/or
- b. Failed to warn that cow's milk-based products are unsafe and/or contraindicated for premature infants like the Injured Infant; and/or
- c. Inserted warnings and instructions on their products that are severely inadequate, vague, confusing, and provide a false sense of security in that they warn and instruct specifically on certain conditions, but do not warn of the significantly increased risk of NEC and death; and/or

- d. Failed to insert a large and prominent “black box”-type warning that their cow’s milk-based products are known to significantly increase the risk of NEC and death when compared to breast milk in premature infant; and/or
- e. Failed to disclose well-researched and well-established studies that linked cow’s milk-based products to NEC and death in premature infants; and/or
- f. Failed to insert a warning or instruction to healthcare professionals and other medical staff in the hospital that parents should be provided information necessary to make an informed choice about whether to allow their babies to be fed the Defendant Manufacturers’ products, notwithstanding their substantial risks; and/or
- g. Failed to provide a warning in a method reasonably calculated or expected to reach the parents of newborns, like the Plaintiff Parent; and/or
- h. Failed to provide statistical evidence showing the magnitude of increased risk of NEC in premature infants associated with cow’s milk-based products.

79. Abbott’s and Mead’s products contained cow’s milk at the time they left the manufacturing facility.

80. As a direct and proximate result of the inadequacy of the warnings and the pervasive marketing campaigns suggesting the safety and necessity of the Defendant Manufacturers’ products, the Injured Infant were fed cow’s milk-based products, which caused them to develop NEC.

81. The unwarned-of risks are not of a kind that an ordinary consumer would expect. Had physicians and medical staff known of the extreme risk associated with feeding premature infants cow’s milk-based formula, they would not have fed the Injured Infant those products. Had the

Plaintiff Parent known of the significant risks of feeding the Injured Infant cow's milk-based formula, they would not have allowed such products to be fed to the Injured Infant.

82. As a further direct result, the Plaintiff Parent suffered significant emotional distress, loss of income, and/or other harms. Her life has been significantly affected by the Injured Infant's injuries.

WHEREFORE, Plaintiff demands judgment against the Defendant Manufacturers as follows:

- a. For compensatory damages in an amount to be proven at trial and in excess of \$50,000 and this Court's arbitrational limit;
- b. For damages for past, present, and future emotional distress, loss of enjoyment of life, pain and suffering, mental anguish, and other non-economic losses sustained as a result of the Defendants Manufacturers' conduct;
- c. For past, present, and future out-of-pocket costs, lost income and/or lost revenue, and/or lost profits, and/or lost business opportunity, lost earning capacity, and costs related to medical or mental health treatment which have or may be recommended;
- d. For punitive damages in excess of \$50,000 and this Court's arbitrational limit resulting from the Defendants Manufacturers' oppressive, fraudulent, and/or malicious conduct, as permitted by law;
- e. For interest as permitted by law;
- f. For attorney's fees, expenses, and recoverable costs incurred in connection with this action; and
- g. For such other and further relief as the Court deems proper.

**COUNT III: NEGLIGENCE
(Against Abbott and Mead)**

83. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.

84. Abbott and Mead, as the manufacturers and/or sellers of the products at issue in this litigation, owed a duty to the consuming public in general, and the Plaintiff Parent in particular, to exercise reasonable care to design, test, manufacture, inspect, and distribute a product free of unreasonable risk of harm to users, when such products are used in their intended manner and for their intended purpose.

85. At all times relevant to this action, the Injured Infant's healthcare professionals and medical staff used the products at issue in their intended manner and for their intended purpose.

86. Abbott and Mead, directly or indirectly, negligently, and/or defectively made, created, manufactured, designed, assembled, tested, marketed, sold, and/or distributed the cow's milk-based infant products at issue in this litigation and thereby breached their duty to the general public and the Plaintiff Parent.

87. Specifically, although Abbott and Mead knew or reasonably should have known at the time of production that their cow's milk-based infant products significantly increased the risk of NEC, serious injury, and death, they failed to act in a reasonably prudent manner and breached their duty by:

- a. Failing to warn that cow's milk-based products significantly increase the risk of NEC, severe injury, and death for the Injured Infant; and/or
- b. Failing to warn that cow's milk-based products are unsafe and/or contraindicated for premature infants like the Injured Infant; and/or

- c. Inserting warnings and instructions that are severely inadequate, vague, confusing, and provide a false sense of security in that they warn and instruct specifically on certain conditions, but do not warn of the significantly increased risk of NEC and death; and/or
- d. Failing to insert a large and prominent “black box”-type warning that their cow’s milk-based products are known to significantly increase the risk of NEC and death when compared to breast milk in premature infants; and/or
- e. Failing to provide well-researched and well-established studies that linked cow’s milk-based products to NEC and death in premature infants; and/or
- f. Failing to insert a warning or instruction to healthcare professionals and other medical staff in the hospital that parents should be provided information necessary to make an informed choice about whether to allow their babies to be fed the Defendant Manufacturers’ products, notwithstanding their substantial risks; and/or
- g. Failing to provide a warning in a method reasonably calculated/expected to reach the parents of newborns, like the Plaintiff Parent; and/or
- h. Failing to provide statistical evidence showing the magnitude of increased risk of NEC in premature infants associated with cow’s milk-based products.

88. In addition, although Abbott and Mead knew or reasonably should have known at the time of production that their cow’s milk-based products significantly increased the risk of NEC, serious injury, and death, they failed to act in a reasonably prudent manner and breached their duty by failing to perform the necessary process of data collection, detection, assessment, monitoring, prevention, and reporting or disclosure of adverse outcomes in infants who ingest their products.

89. As a direct and proximate result of the Defendant Manufacturers' failure to act in a reasonably prudent manner and their breach of duty, the Injured Infant was fed cow's milk-based products, which caused and/or increased the risk of their developing NEC.

90. Had Abbott and Mead satisfied their duties to the consuming public in general, the Injured Infant would not have been exposed to their unreasonably dangerous cow's milk-based products.

91. As a further direct result, the Plaintiff Parent suffered significant emotional distress, loss of income, and/or other harms. Her life has been significantly affected by the Injured Infant's injuries.

WHEREFORE, Plaintiff demands judgment against the Defendant Manufacturers as follows:

- a. For compensatory damages in an amount to be proven at trial and in excess of \$50,000 and this Court's arbitrational limit;
- b. For damages for past, present, and future emotional distress, loss of enjoyment of life, pain and suffering, mental anguish, and other non-economic losses sustained as a result of the Defendants Manufacturers' conduct;
- c. For past, present, and future out-of-pocket costs, lost income and/or lost revenue, and/or lost profits, and/or lost business opportunity, lost earning capacity, and costs related to medical or mental health treatment which have or may be recommended;
- d. For punitive damages in excess of \$50,000 and this Court's arbitrational limit resulting from the Defendants Manufacturers' oppressive, fraudulent, and/or malicious conduct, as permitted by law;
- e. For interest as permitted by law;
- f. For attorney's fees, expenses, and recoverable costs incurred in connection with this action; and

g. For such other and further relief as the Court deems proper.

**COUNT IV: INTENTIONAL MISREPRESENTATION
(Against Abbott and Mead)**

92. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.

93. At all times relevant to this action, the Injured Infant consumed the Defendant Manufacturers' products in their intended manner and for their intended purpose.

94. Abbott and Mead, as the manufacturers and/or sellers of the infant products at issue in this litigation, owed a duty to the consuming public in general, and the Plaintiff Parent in particular, to provide truthful, accurate, fulsome information about the risks and benefits of using their products when used in the intended manner and for the intended purpose.

95. Abbott and Mead breached their duty through misrepresentations made to consumers, physicians, and medical staff in their advertising and promotional materials, as described in previous paragraphs and incorporated herein, each of whom were foreseeable and intended recipients of this information.

96. Specifically, upon information and belief, Abbott and Mead made the following false statements of material fact on an ongoing and repeated basis and prior to the time the Injured Infant was fed their products:

- a. That their cow's milk-based products were safe and beneficial for premature infants when they knew or should have known that their products were unreasonably dangerous and cause NEC, serious injury, and death in premature infants; and/or
- b. That their cow's milk-based products were necessary to the growth and nutrition of premature infants, when they knew or should have known that their products were not necessary to achieve adequate growth; and/or

- c. That their products have no serious side effects, when they knew or should have known the contrary to be true; and/or
- d. That cow's milk-based products were safe for premature infants; and/or
- e. That cow's milk-based products were necessary for optimum growth; and/or
- f. That cow's milk-based products were similar or equivalent to breast milk; and/or
- g. That their products were safe and more like breast milk than other infant products and that they had removed the harmful ingredients of cow's milk when, in fact, the cow's milk in their products was still capable of causing NEC, serious injury, and death; and/or
- h. That their products were based on up-to-date science, which made them safe for premature infants; and/or
- i. Omitting the material fact that their products significantly increased the risk of NEC in premature infants.

97. Abbott and Mead knew or reasonably should have known those misrepresentations to be false.

98. The Defendant Manufacturers' misrepresentations were intended to, and in fact did, induce physicians and medical staff, including the Injured Infant's physicians and medical staff, to provide their infant products to babies, including the Injured Infant.

99. The Plaintiff Parent was not aware that these misrepresentations were false and justifiably relied on them. The Defendant Manufacturers' misrepresentations induced the Plaintiff Parent to allow their children to be fed Abbott's and Mead's infant products, in reliance on all the messaging they received about formula feeding, including, directly or indirectly, the Defendant Manufacturers' messaging. Had Abbott and Mead not committed these intentional

misrepresentations, the Injured Infant would not have been exposed to the Defendant Manufacturers' unreasonably dangerous cow's milk-based products.

100. As a direct and proximate result, Abbott's and Mead's products were fed to the Injured Infant, which caused and/or increased risk of their developing NEC and subsequent injuries.

101. As a further direct result, the Plaintiff Parent suffered significant emotional distress, loss of income, and/or other harms. Her life has been significantly affected by the Injured Infant's injuries.

WHEREFORE, Plaintiff demands judgment against the Defendant Manufacturers as follows:

- a. For compensatory damages in an amount to be proven at trial and in excess of \$50,000 and this Court's arbitrational limit;
- b. For damages for past, present, and future emotional distress, loss of enjoyment of life, pain and suffering, mental anguish, and other non-economic losses sustained as a result of the Defendants Manufacturers' conduct;
- c. For past, present, and future out-of-pocket costs, lost income and/or lost revenue, and/or lost profits, and/or lost business opportunity, lost earning capacity, and costs related to medical or mental health treatment which have or may be recommended;
- d. For punitive damages in excess of \$50,000 and this Court's arbitrational limit resulting from the Defendant Manufacturers' oppressive, fraudulent, and/or malicious conduct, as permitted by law;
- e. For interest as permitted by law;
- f. For attorney's fees, expenses, and recoverable costs incurred in connection with this action; and
- g. For such other and further relief as the Court deems proper.

**COUNT V: NEGLIGENT MISREPRESENTATIONS
(Against Abbott and Mead)**

102. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.

103. At all times relevant to this action, the Injured Infant consumed the products at issue in their intended manner and for their intended purpose.

104. Abbott and Mead, as the manufacturers and/or sellers of the products at issue in this litigation, owed a duty to the consuming public in general, and the Plaintiff Parent in particular, to provide truthful, accurate, and complete information about the risks and benefits of using their products when used in the intended manner and for the intended purpose.

105. In the course of their business, Abbott and Mead breached their duty through misrepresentations made to consumers, physicians, and medical staff in their advertising and promotional materials, as described in previous paragraphs and incorporated herein, each of whom were foreseeable recipients of this information.

106. Specifically, upon information and belief, Abbott and Mead made the following false statements of material fact on an ongoing and repeated basis and prior to the time the Injured Infant was fed their products:

- a. That their cow's milk-based products were safe and beneficial for premature infants when they knew or should have known that their products were unreasonably dangerous and cause NEC, serious injury, and death in premature infants; and/or
- b. That their cow's milk-based products were necessary to the growth and nutrition of premature infants, when they knew or should have known that their products were not necessary to achieve adequate growth; and/or

- c. That their products have no serious side effects, when they knew or should have known the contrary to be true; and/or
- d. That cow's milk-based products were safe for premature infants; and/or
- e. That cow's milk-based products were necessary for optimum growth; and/or
- f. That cow's milk-based products were similar or equivalent to breast milk; and/or
- g. That their products were safe and more like breast milk than other infant products and that they had removed the harmful ingredients of cow's milk when, in fact, the cow's milk in their products was still capable of causing NEC, serious injury, and death; and/or
- h. That their products were based on up-to-date science, which made them safe for premature infants; and/or
- i. Omitting the material fact that their products significantly increased the risk of NEC in premature infants.

107. Abbott and Mead were negligent or careless in not determining those representations to be false.

108. The Defendant Manufacturers' misrepresentations were intended to and did in fact induce physicians and medical staff, including the Injured Infant's physicians and medical staff, to provide their products to babies, including the Injured Infant.

109. The Defendant Manufacturers' misrepresentations induced, and were intended to induce, the Plaintiff Parent to allow their child to be fed Abbott's and Mead's infant products, in justifiable reliance on all the messaging they received about formula feeding, including, directly or indirectly, the Defendant Manufacturers' messaging. Had Abbott and Mead not committed these negligent

misrepresentations, the Injured Infant would not have been exposed to their unreasonably dangerous cow's milk-based products.

110. As a direct and proximate result, Abbott's and Mead's products were fed to the Injured Infant, which caused and/or increased of their developing NEC and subsequent injuries.

111. As a further direct result, the Plaintiff Parent suffered significant emotional distress, loss of income, and/or other harms. Her life has been significantly affected by the Injured Infant's injuries.

WHEREFORE, Plaintiff demands judgment against the Defendant Manufacturers as follows:

- a. For compensatory damages in an amount to be proven at trial and in excess of \$50,000 and this Court's arbitrational limit;
- b. For damages for past, present, and future emotional distress, loss of enjoyment of life, pain and suffering, mental anguish, and other non-economic losses sustained as a result of the Defendants Manufacturers' conduct;
- c. For past, present, and future out-of-pocket costs, lost income and/or lost revenue, and/or lost profits, and/or lost business opportunity, lost earning capacity, and costs related to medical or mental health treatment which have or may be recommended;
- d. For punitive damages in excess of \$50,000 and this Court's arbitrational limit resulting from the Defendant Manufacturers' oppressive, fraudulent, and/or malicious conduct, as permitted by law;
- e. For interest as permitted by law;
- f. For attorney's fees, expenses, and recoverable costs incurred in connection with this action; and
- g. For such other and further relief as the Court deems proper.

**COUNT VI: FAILURE TO WARN
(Against Penn Medicine and Pennsylvania Hospital)**

112. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.

113. Penn Medicine and Pennsylvania Hospital as purchaser, supplier, and/or distributor of the products at issue in this litigation, owed a duty to the consuming public in general, and the Plaintiff Parent in particular, to purchase, supply, and distribute products that were free of unreasonable risk of harm when used in their intended manner and for their intended purpose, and/or to formulate, adopt, and enforce adequate rules and policies for the same.

114. At all times relevant to this action, the Injured Infant used the cow's milk-based products purchased, supplied, and/or distributed by Penn Medicine and Pennsylvania Hospital in their intended manner and for their intended purpose.

115. Penn Medicine and Pennsylvania Hospital employed or contracted with the healthcare professionals and medical staff at Pennsylvania Hospital, managing these individuals during their treatment of the Injured Infant.

116. Penn Medicine and Pennsylvania Hospital negligently and recklessly supplied and distributed the Defendant Manufacturers' milk-based infant feeding products to these healthcare professionals and medical staff for use on premature infants, including the Injured Infant.

117. Moreover, at all relevant times, Penn Medicine and Pennsylvania Hospital knowingly authorized the Defendant Manufacturers' sales representatives to market, advertise, distribute, and/or sell their products at Pennsylvania Hospital. The Defendant Manufacturers' sales representatives were encouraged to interact with Pennsylvania Hospital's healthcare professionals and medical staff. These interactions provided the Defendant Manufacturers' sales representatives an opportunity to co-opt Pennsylvania Hospital's healthcare professionals and medical staff into

assisting with the marketing, distribution, and/or sale of the Defendant Manufacturers' unreasonably dangerous products to consumers, such as the Plaintiff Parent.

118. Penn Medicine and Pennsylvania also knowingly allowed the Defendant Manufacturers' sales representatives to routinely misrepresent the risks and benefits of Defendants' products to Pennsylvania Hospital's healthcare professionals and medical staff, including the misrepresentation that premature babies would not grow adequately with human milk and human milk products and that use of donor milk was not advised for premature infants.

119. Penn Medicine and Pennsylvania Hospital knew or reasonably should have known at the time that they acquired, distributed, and supplied the Defendant Manufacturers' cow's milk-based infant products that these products significantly increased the risk of NEC, serious injury, and death.

120. Nonetheless, Penn Medicine and Pennsylvania Hospital acted negligently, recklessly and breached its duty by:

- a. Failing to warn that cow's milk-based products significantly increase the risk of NEC, severe injury, and death in those babies; and/or
- b. Failing to warn that cow's milk-based products are unsafe and/or contraindicated for premature infants like the Injured Infant; and/or
- c. Failing to warn or instruct its healthcare professionals and medical staff on the information that should be provided to parents in order to make an informed choice about whether to allow their babies to be fed the Defendant Manufacturers' products, notwithstanding their substantial risk; and/or

- d. Failing to provide its healthcare professionals and medical staff with the well-researched and well-established studies that link cow's milk-based products to NEC and death in premature infants; and/or
- e. Failing to provide a warning in a method reasonably calculated/expected to reach the parents of newborns; and/or
- f. Failing to provide statistical evidence showing the magnitude of increased risk of NEC in premature infants associated with cow's milk-based products; and/or
- g. Failing to prevent the Defendant Manufacturers' sales representatives from misrepresenting to Pennsylvania Hospital's healthcare professionals and medical staff that premature babies would not grow adequately with human milk and human milk products and that use of donor milk was not advised for premature infants.

121. Reasonable hospitals under the same or similar circumstances would have warned of the above risks, would have instructed their healthcare professionals and medical staff—as well as patients—on the safe use of the Defendant Manufacturers' products, and would have restricted the ability of the Defendant Manufacturers' sales representatives to market the Defendant Manufacturers' unreasonably dangerous products without adequate warning.

122. Penn Medicine and Pennsylvania Hospital knew or reasonably should have known that its medical professionals and the parents of premature infants, including the Plaintiff Parent, would not have realized the risks associated with feeding cow's milk-based formula to premature infants.

123. Had Penn Medicine and Pennsylvania Hospital exercised reasonable care by satisfying its duty to warn its medical providers and patients about the Defendant Manufacturers' unreasonably dangerous products, the Injured Infant would not have been exposed to the Defendant Manufacturers' cow's milk-based products.

124. As a direct and proximate result of Penn Medicine and Pennsylvania Hospital's failure to warn of the danger posed by the Defendant Manufacturers' unreasonably dangerous cow's milk-based products, the Injured Infant was fed the Defendant Manufacturers' cow's milk-based products, which caused and/or increased the risk of developing NEC and significant injuries.

125. As a further direct and proximate result of Penn Medicine and Pennsylvania failure to warn of the Defendant Manufacturers' unreasonably dangerous products, the Plaintiff Parent suffered significant emotional distress, loss of income, and/or other harms. Her life has been significantly affected by the Injured Infant's injuries.

WHEREFORE, Plaintiff demands judgment against Penn Medicine and Pennsylvania Hospital as follows:

- a. For compensatory damages in an amount to be proven at trial and in excess of \$50,000 and this Court's arbitrational limit;
- b. For damages for past, present, and future emotional distress, loss of enjoyment of life, pain and suffering, mental anguish, and other non-economic losses sustained as a result of Penn Medicine's conduct;
- c. For past, present, and future out-of-pocket costs, lost income and/or lost revenue, and/or lost profits, and/or lost business opportunity, lost earning capacity, and costs related to medical or mental health treatment which have or may be recommended;
- d. For punitive damages in excess of \$50,000 and this Court's arbitrational limit resulting from Penn Medicine and Pennsylvania Hospital's oppressive, reckless, and/or malicious conduct, as permitted by law;
- e. For interest as permitted by law;

- f. For attorney's fees, expenses, and recoverable costs incurred in connection with this action; and
- g. For such other and further relief as the Court deems proper.

**COUNT VII: CORPORATE LIABILITY OF HEALTH-CARE PROVIDER
(Against Penn Medicine and Pennsylvania Hospital)**

126. Plaintiff incorporates by references each of the preceding paragraphs as if fully set forth herein.

127. At all relevant times, Penn Medicine and Pennsylvania Hospital owed a duty of care to the Injured Infant to ensure their safety and well-being while the Injured Infant was under the care of Pennsylvania Hospital staff. Specifically, Penn Medicine and Pennsylvania Hospital had a duty to the Injured Infant to formulate, adopt, and enforce adequate rules and policies to ensure quality care for the Injured Infant. Further, Penn Medicine and Pennsylvania Hospital owed a duty to the Injured Infant to oversee its healthcare professionals and medical staff that provided patient care to the Injured Infant.

128. Penn Medicine and Pennsylvania Hospital owed a duty to its patients, and the Injured Infant in particular, to formulate, adopt, and enforce adequate rules and policies for the purchase, supply, distribution, and use of products that were free of unreasonable risk of harm when used in their intended manner and for their intended purpose and ensured quality care for the Injured Infant.

129. At all times relevant to this action, the Injured Infant used the cow's milk-based products purchased, supplied, and/or distributed by Penn Medicine and Pennsylvania Hospital in their intended manner and for their intended purpose.

130. Moreover, at all relevant times, Penn Medicine and Pennsylvania Hospital knowingly authorized the Defendant Manufacturers' sales representatives to market, advertise, distribute,

and/or sell their products at Pennsylvania Hospital. The Defendant Manufacturers' sales representatives were encouraged to interact with Pennsylvania Hospital's healthcare professionals and medical staff. These interactions provided the Defendant Manufacturers' sales representatives an opportunity to co-opt Pennsylvania Hospital's healthcare professionals and medical staff into assisting with the marketing, distribution, and/or sale of the Defendant Manufacturers' unreasonably dangerous products.

131. Penn Medicine and Pennsylvania Hospital also knowingly allowed the Defendant Manufacturers' sales representatives to routinely misrepresent the risks and benefits of Defendants' products to Pennsylvania Hospital's healthcare professionals and medical staff, including the misrepresentation that premature babies would not grow adequately with human milk and human milk products and that use of donor milk was not advised for premature infants.

132. Penn Medicine and Pennsylvania Hospital knew or reasonably should have known at the time that it formulated, adopted, and enforced its rules for the acquisition, distribution, and supply of the Defendant Manufacturers' cow's milk-based infant products, including the access afforded the Defendant Manufacturer's sales representatives, that these products significantly increased the risk of NEC, serious injury, and death for premature infants.

133. Penn Medicine and Pennsylvania Hospital knew or reasonably should have known that its medical professionals and the parents of premature infants, including the Plaintiff Parent, would not have realized the risks associated with feeding cow's milk-based formula to premature infants.

134. Nonetheless, Penn Medicine and Pennsylvania Hospital acted negligently, recklessly and breached its duty by:

- a. Failing to formulate, adopt, and enforce adequate rules and policies that would have restricted the use of cow's milk-based products for feeding premature babies; and/or
- b. Failing to formulate, adopt, and enforce adequate rules and policies that warned the Plaintiff Parent that cow's milk-based products significantly increase the risk of NEC, severe injury, and death in premature babies, like the Injured Infant; and/or
- c. Failing to formulate, adopt, and enforce adequate rules and policies that warned its healthcare professionals and medical staff that cow's milk-based products are unsafe and/or contraindicated for premature babies like the Injured Infant; and/or
- d. Failing to formulate, adopt, and enforce adequate rules and policies to instruct its healthcare professionals and medical staff on the information that should be provided to parents in order to make an informed choice about whether to allow their babies to be fed the Defendant Manufacturers' products, notwithstanding their substantial risk; and/or
- e. Failing to formulate, adopt, and enforce adequate rules and policies to provide its healthcare professionals and medical staff with the well-researched and well-established studies that link cow's milk-based products to NEC and death in premature infants; and/or
- f. Failing to formulate, adopt, and enforce adequate rules and policies to ensure a warning in a method reasonably calculated/expected to reach the parents of newborns, like the Plaintiff Parent; and/or
- g. Failing to formulate, adopt, and enforce adequate rules and policies to prevent the Defendant Manufacturers' sales representative from misrepresenting to

Pennsylvania Hospital's healthcare professionals and medical staff that premature babies would not grow adequately with human milk and human milk products and that use of donor milk was not advised for premature infants; and/or

- h. Failing to establish a donor milk program that was sufficient to meet the needs of the premature babies, like the Injured Infant.

135. A reasonable hospital under the same or similar circumstances would have formulated, adopted, and enforced adequate policies, and rules to restrict the feeding of cow's milk-based products to premature babies, including developing an adequate donor milk program, instructing its healthcare professionals and medical staff on the safe use of Defendants Manufacturers' cow's milk-based products, and restricting the marketing of the Defendant Manufacturers' unreasonably dangerous products to its healthcare professionals, medical staff, and parents of premature infants under its care.

136. Had Penn Medicine and Pennsylvania Hospital exercised reasonable care by satisfying its duty to formulate, adopt, and enforce adequate rules and policies to ensure the quality care of its patients, the Injured Infant would not have been exposed to the Defendant Manufacturers' cow's milk-based products.

137. As a direct and proximate result of Penn Medicine and Pennsylvania Hospital failure to formulate and enforce adequate policies and rules related to the danger posed by the Defendant Manufacturers' unreasonably dangerous cow's milk-based products, the Injured Infant was fed the Defendant Manufacturers' cow's milk-based products, which caused and/or increased the risk of developing NEC and significant injuries.

138. As a further direct and proximate result of Penn Medicine and Pennsylvania Hospital negligent and reckless conduct the Plaintiff Parent suffered significant emotional distress, loss of

income, and/or other harms. Her life has been significantly affected by the Injured Infant's injuries.

139. In the alternative, Penn Medicine and Pennsylvania Hospital owed a duty to its patients, and the Injured Infant in particular, to oversee the practicing healthcare professionals and medical staff that provided the products at issue to infants under Pennsylvania Hospital's care, including the Injured Infant.

140. Penn Medicine and Pennsylvania Hospital employed or contracted with the healthcare professionals and medical staff at Pennsylvania Hospital and was responsible for overseeing those individuals during their treatment of the Injured Infant.

141. Nonetheless, Penn Medicine and Pennsylvania Hospital acted negligently, recklessly and breached its duty by:

- a. Failing to oversee its healthcare professionals and medical staff on their use of cow's milk-based products for feeding premature babies; and/or
- b. Failing to warn or instruct its healthcare professionals and medical staff that cow's milk-based products significantly increase the risk of NEC, severe injury, and death in those babies; and/or
- c. Failing to warn or instruct its healthcare professionals and medical staff that cow's milk-based products are unsafe and/or contraindicated for premature babies like the Injured Infant; and/or
- d. Failing to oversee its healthcare professionals and medical staff to restrict their feeding of cow's milk-based products to premature babies; and/or
- e. Failing to warn or instruct its healthcare professionals and medical staff on the information that should be provided to parents in order to make an informed choice

about whether to allow their babies to be fed the Defendant Manufacturers' products, notwithstanding their substantial risk; and/or

- f. Failing to provide its healthcare professionals and medical staff with the well-researched and well-established studies that link cow's milk-based products to NEC and death in premature infants; and/or
- g. Failing to provide its healthcare professionals and medical staff with warnings about the dangers of the Defendants' Manufacturers products in a method reasonably calculated/expected to reach the parents of newborns; and/or
- h. Failing to provide statistical evidence to its healthcare professionals and medical staff showing the magnitude of increased risk of NEC in premature infants associated with cow's milk-based products; and/or
- i. Failing to oversee its healthcare professionals and medical staff to ensure that the Defendant Manufacturers' sales representatives' misrepresentations that premature babies would not grow adequately with human milk and human milk products and that use of donor milk was not advised for premature infants had not influenced the use and/or misuse of the Defendant Manufacturers' products.

142. A reasonable hospital under the same or similar circumstances would have warned of the above risks, would have instructed its healthcare professionals and medical staff on the safe use of the Defendant Manufacturers' products, and would have restricted the ability of the Defendant Manufacturers' sales representatives to market the Defendant Manufacturers' unreasonably dangerous products without adequate warning.

143. A reasonable hospital under the same or similar circumstances would have overseen and managed its healthcare professionals and medical staff to ensure that they received proper training and updating on the risks associated with feeding cow's milk-based formula to premature infants.

144. Had Penn Medicine and Pennsylvania Hospital exercised reasonable care by satisfying its duty to oversee its healthcare professionals and medical staff who provide patient care, the Injured Infant would not have been exposed to the Defendant Manufacturers' cow's milk-based products.

145. As a direct and proximate result of Penn Medicine and Pennsylvania Hospital's failure to oversee its healthcare professionals and medical staff on the danger posed by the Defendant Manufacturers' unreasonably dangerous cow's milk-based products, the Injured Infant was fed the Defendant Manufacturers' cow's milk-based products, which caused and/or increased the risk of developing NEC and significant injuries.

146. As a further direct and proximate result of Penn Medicine and Pennsylvania Hospital's negligent and reckless conduct, , the Plaintiff Parent suffered significant emotional distress, loss of income, and/or other harms. Her life has been significantly affected by the Injured Infant's injuries.

WHEREFORE, Plaintiff demands judgment against Penn Medicine and Pennsylvania Hospital as follows:

- a. For compensatory damages in an amount to be proven at trial and in excess of \$50,000 and this Court's arbitrational limit;
- b. For damages for past, present, and future emotional distress, loss of enjoyment of life, pain and suffering, mental anguish, and other non-economic losses sustained as a result of Penn Medicine and Pennsylvania Hospital's conduct;

- c. For past, present, and future out-of-pocket costs, lost income and/or lost revenue, and/or lost profits, and/or lost business opportunity, lost earning capacity, and costs related to medical or mental health treatment which have or may be recommended;
- d. For punitive damages in excess of \$50,000 and this Court's arbitrational limit resulting from Penn Medicine's oppressive, fraudulent, and/or malicious conduct, as permitted by law;
- e. For interest as permitted by law;
- f. For attorney's fees, expenses, and recoverable costs incurred in connection with this action; and
- g. For such other and further relief as the Court deems proper.

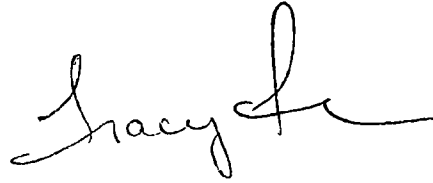
DEMAND FOR JURY TRIAL

147. Plaintiff hereby demands a jury trial for all claims triable.

Dated: March 24, 2022

Respectfully submitted,

ANAPOL WEISS



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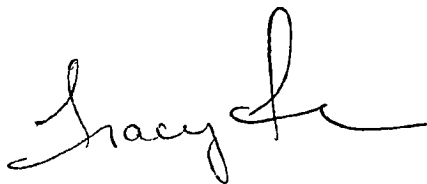
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CERTIFICATE OF SERVICE

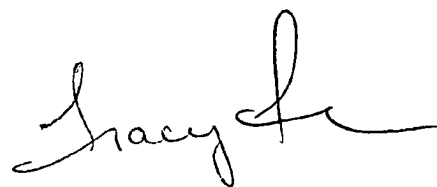
I hereby certify that on March 24, 2022, I electronically filed the foregoing document with the Clerk of the Court using CM/ECF and that the foregoing document is being served on all counsel of record or parties registered to receive CM/ECF Electronic Filings.

A handwritten signature in black ink, appearing to read "Tracy Finken", written over a horizontal line.

Tracy Finken

VERIFICATION

I, the undersigned, Tracy Finken, verify that the statements made in this document are true and correct to the best of my knowledge, information, and belief. I understand that false statements herein are made subject to the penalties of 18 Pa. C.S. §4904, relating to unsworn falsification to authorities.

A handwritten signature in black ink, appearing to read "Tracy Finken", written over a horizontal line.

Date: March 24, 2022

Tracy Finken

EXHIBIT “B”

MEDICAL SCIENCE

Breast milk and neonatal necrotising enterocolitis

A. LUCAS T. J. COLE

In a prospective multicentre study on 926 preterm infants formally assigned to their early diet, necrotising enterocolitis developed in 51 (5.5%). Mortality was 26% in stringently confirmed cases. In exclusively formula-fed babies confirmed disease was 6–10 times more common than in those fed breast milk alone and 3 times more common than in those who received formula plus breast milk. Pasteurised donor milk seemed to be as protective as raw maternal milk. Among babies born at more than 30 weeks' gestation confirmed necrotising enterocolitis was rare in those whose diet included breast milk; it was 20 times more common in those fed formula only. Other risk factors included very low gestational age, respiratory disease, umbilical artery catheterisation, and polycythaemia. In formula-fed but not breast-milk-fed infants, delayed enteral feeding was associated with a lower frequency of necrotising enterocolitis. With the fall in the use of breast milk in British neonatal units, exclusive formula feeding could account for an estimated 500 extra cases of necrotising enterocolitis each year. About 100 of these infants would die.

Lancet 1990; **336**: 1519–23.

Introduction

Necrotising enterocolitis is the most common serious gastrointestinal disease seen in neonatal intensive care units, with a reported mortality in well-established cases of 20–40%.¹ The causes have been elusive. Prematurity or low birthweight are the most consistently reported associated factors,² but up to 10% of cases occur in term babies.³ Some studies suggest a strong relation between necrotising enterocolitis and factors that could cause gut ischaemia or hypoxia;^{4,6} others fail to find these associations.^{1,2,7} An infective aetiology has been suggested by case clustering, the presence of a predominant organism in outbreaks, the effectiveness of standard infectious disease control methods in epidemics,^{8,9} and the apparent prophylactic value of oral immunoglobulin.¹⁰ Nevertheless, no single organism has proved to be the cause¹¹ and most of the microorganisms identified are present in normal gut flora. The importance of enteral feeding as a risk factor has been emphasised,^{3,12–14} but 5–10% of cases occur in babies who have never been

enterally fed.^{1,3} Further suggested factors related to feeding include early initiation of enteral feeds,¹⁴ rapid escalation of feed volumes,¹³ and hyperosmolar feeding,^{15,16} but others doubt their importance.^{4,17} Several small studies and anecdotal observations^{18–20} have suggested that breast milk is protective. This idea is supported by findings in a rat model that live milk leucocytes are prophylactic.^{21,22} Nevertheless, necrotising enterocolitis can occur in infants fed exclusively on fresh, frozen, or pasteurised breast milk.^{4,14,23}

It seems that no single aetiological factor explains necrotising enterocolitis and that the mucosal lesion can be provoked in several ways. An important question, however, is whether there are any important risk factors that can be avoided readily in clinical practice. Feeding policy is the factor most amenable to manipulation. In our prospective, randomised, multicentre study of dietary management in 926 infants,²⁴ we have re-explored the relation between early diet or feeding practice and the frequency of necrotising enterocolitis.

Subjects and methods

926 infants with birthweights below 1850 g (mean 1370 [SD 320] g; mean gestation 31 [3] weeks) were recruited in five centres, to test whether early diet, randomly assigned, affected short-term morbidity and long-term outcome. Necrotising enterocolitis was identified as a major short-term outcome response.

There were two parallel dietary studies. In three centres (study A) infants were randomly assigned to pasteurised banked donated breast milk or a nutrient-enriched preterm formula ('Osterprem', Farley Health Products Ltd, Nottingham, UK). The randomisation was stratified according to whether the mother provided breast milk for her own infant. Thus, donor milk and preterm formula could be compared as sole diets (in infants whose mothers did not provide their own milk) or as supplements to breast milk. In two further centres (study B) the same randomisation procedure was used to compare infants fed a standard "term" formula ('Ostermilk', Farley Health Products Ltd) or the preterm formula, again as sole diets or as supplements to mother's milk. When the trial diets (donor milk, term formula, or preterm formula) were used as a supplement to maternal breast milk, the median intake of mother's milk was 48% (interquartile range 10–86%) with no difference between diet groups. Randomisation is described elsewhere;²⁴ it took place within 48 h of birth, independently in each

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centre, and assignments were based on permuted blocks of variable length.

Detailed composition of the formulas is available from the manufacturers. Briefly, for each 100 ml the standard formula contained 1.45 g protein and 286 kJ (68 kcal), and the preterm formula 2.0 g protein and 336 kJ (80 kcal). The preterm formula was also enriched in sodium, calcium, phosphorus, copper, zinc, vitamins D, E, and K, water-soluble vitamins, carnitine, and taurine. The osmolality of both formulas was 300 mosmol/kg. Donor breast milk was pasteurised and frozen. Mother's milk was not pasteurised and was fed untreated or after a period of refrigeration or, occasionally, freezing.

Various classifications have been proposed for necrotising enterocolitis.^{25,26} We have used the British Association for Perinatal Pediatrics classification based on features of the disease in 165 cases in 54 British centres.²⁶ Grade 1 cases had at least two of the following features: pneumatosis intestinalis on abdominal radiograph; abdominal distension or an abdominal radiograph showing gaseous distension or frothy appearance of bowel lumen (or both); blood in the stool; lethargy, hypotonia, or apnoeic episodes, or a combination of the three. Grade 2 cases had, as well as grade 1 features, one or more of: abdominal tenderness or rigidity; tissue (mucosa) in stool; abnormal bleeding with trauma; spontaneous bleeding; peripheral white blood cell count below $6 \times 10^9/l$ at the time of illness; peripheral platelet count below $100 \times 10^9/l$ at the time of illness; or an abdominal radiograph showing gas in the portal vein or free air in the abdomen. The cases were further divided into confirmed cases (with classic radiological features [pneumatosis intestinalis, gas in the portal venous system, or free air in the abdomen] or with necrotising enterocolitis established surgically or at necropsy) and unconfirmed cases.

The frequency of necrotising enterocolitis was examined among the randomised diet groups. In the main analysis, however, necrotising enterocolitis was examined in three non-randomised enteral feed groups—human milk only (donor or donor plus mother's milk), formula (term or preterm) as a supplement to mother's milk, and formula only. Extensive logistic regression analyses were used—to adjust for potential confounding factors in the comparison between non-randomised feed groups; to quantify other risk factors for necrotising enterocolitis; and to identify interactions between diet and non-dietary factors. For most analyses, data are presented for all cases of necrotising enterocolitis and for confirmed cases only.

Results

Clinical features of necrotising enterocolitis developed in 51 of the 926 infants studied, and the diagnosis was more stringently "confirmed" in 31 (table 1). All the infants who required surgery or who died had grade 2 confirmed disease. Of the confirmed cases, 35% needed surgery, and necrotising enterocolitis was considered the principal cause of death in 26%. All infants in whom necrotising enterocolitis developed had received enteral feeds.

The clinical characteristics of the study population and the higher frequency of necrotising enterocolitis at low gestation and with respiratory disease are shown in table II.

The only formal randomised comparison of human milk and formula feeding on the incidence of necrotising enterocolitis was that of infants fed exclusively on donor breast milk or on preterm formula. Among the 86 infants exclusively fed on donor milk there were 3 (4%) cases (1 [1%] confirmed cases) and among the 76 fed exclusively on preterm formula there were 6 (8%) cases (4 [5%] confirmed); the odds ratios were 2.4 (95% CI 0.6–9.8) for all cases and 4.7 (0.5–43) for confirmed cases. However, the sample size was not large enough to detect a difference smaller than ten-fold in frequency of necrotising enterocolitis between these groups with adequate power. In study A as a whole there were 11 (43%) cases among the 253 infants who received donor milk alone or with maternal milk

TABLE I—OCCURRENCE AND OUTCOME OF NECROTISING ENTEROCOLITIS

—	No of babies (% of total)	No (% of group) who required surgery	No (% of group) who died
Grade 1			
Unconfirmed	16 (1.7%)	0	0
Confirmed	9 (1.0%)	0	0
Grade 2			
Unconfirmed	4 (0.4%)	0	0
Confirmed	22 (2.4%)	11 (50%)	8 (36%)
Total cases	51 (5.5%)	11 (22%)	8 (16%)
Confirmed cases	31 (3.3%)	11 (35%)	8 (26%)

(3 [1.2%] confirmed) and 12 (4.8%) cases among the 249 who received preterm formula as a sole diet or with maternal milk (9 [3.6%] confirmed). The odds ratios were 1.1 (0.5–2.6) for all cases and 3.1 (0.8–11.7) for confirmed cases; however, the 3-fold difference was not significant ($p = 0.07$). In study B the incidence of necrotising enterocolitis was similar in infants fed preterm or term formula either as sole diets (6/81 cases *vs* 11/79 cases) or as supplements to mother's milk (12/213 cases *vs* 16/211 cases).

The 253 subjects fed only human milk ranged from those fed exclusively pasteurised donor milk to those fed almost entirely raw maternal milk. More detailed data modelling (not shown here) confirmed the findings above, that the incidence of necrotising enterocolitis in this subgroup was not affected by the type of breast milk consumed.

Since the occurrence of necrotising enterocolitis was the same in infants fed on different types of breast milk and in infants fed on the two types of formula, we were able to divide the whole population into three large diet groups for comparison—formula only ($n = 236$), formula plus breast milk ($n = 437$), and human milk only ($n = 253$). The formula only group were at a significantly higher risk of necrotising enterocolitis than the other groups (table III). The odds ratio (95% CI) for the comparison of formula only and formula plus mother's milk was 3.0 (1.5–5.7; $p < 0.005$) for all cases and 3.0 (1.4–6.5; $p < 0.005$) for confirmed cases. For the comparison of formula only and breast milk only the odds ratios were 2.5 (1.2–5.2; $p < 0.02$) for all cases and 6.5 (1.9–22; $p < 0.001$) for confirmed cases.

This comparison might have been confounded by the fact that the infants exclusively fed human milk were contributed by only three centres (study A), whereas the formula-fed infants were contributed by all five centres (studies A and B). The frequency of necrotising enterocolitis in preterm formula-fed babies did not, however, differ significantly between studies A and B (7.9 *vs* 7.4%).

TABLE II—CHARACTERISTICS OF STUDY POPULATION

—	All cases	Confirmed cases
No (%) with gestation of:		
25–27 wk ($n = 118$)	20 (16.9%)	12 (10.2%)
28–30 wk ($n = 314$)	18 (5.7%)	11 (3.5%)
< 30 wk ($n = 494$)	13 (2.6%)	8 (1.6%)
No (%) with birthweight of:		
< 1000 g ($n = 144$)	18 (12.5%)	11 (7.6%)
1000–1500 g ($n = 403$)	23 (5.7%)	15 (3.7%)
> 1500 g ($n = 379$)	10 (2.6%)	5 (1.3%)
No (%) of cases with concomitant respiratory disease*†	36/51 (71%)	21/31 (68%)
Median (IQR) enteral feed volume before NEC	410 (140–1160)	390 (160–990)
Median (IQR) day of onset	12 (7–18)	11 (7–18)

NEC = necrotising enterocolitis, IQR = interquartile range.

*338 (39%) of the 875 infants without NEC had concomitant respiratory disease

†Ventilated for > 24 h in the first 72 h

TABLE III—NECROTISING ENTEROCOLITIS BY FEED GROUP

—	n	No (%) of cases	
		All cases	Confirmed cases
Formula only	236	24 (10.2%)	17 (7.2%)
Formula plus mother's milk	437	16 (3.7%)	11 (2.5%)
Human milk only	253	11 (4.3%)	3 (1.2%)

TABLE IV—LOGISTIC REGRESSION MODELS FOR FACTORS SIGNIFICANTLY RELATED TO FREQUENCY OF NECROTISING ENTEROCOLITIS

	All cases		Confirmed cases	
	t	Odds ratio (95% CI)	t	Odds ratio (95% CI)
Formula only vs breast milk + formula	3.37 (p < 0.001)	3.3 (1.6-6.8)	3.05 (p < 0.01)	3.5 (1.5-8.1)
Formula only vs breast milk only	3.06 (p < 0.01)	3.5 (1.5-8.1)	3.74 (p < 0.001)	10.6 (3.0-37.3)
Gestation*	3.06 (p < 0.01)	1.2 (1.1-1.4)	2.43 (p < 0.05)	1.2 (1.0-1.5)
Days of umbilical artery catheterisation†	2.97 (p < 0.01)	1.2 (1.1-1.3)	3.04 (p < 0.01)	1.2 (1.1-1.4)
Day of first feed‡	2.60 (p < 0.01)	1.2 (1.0-1.4)	2.23 (p < 0.05)	1.2 (1.0-1.4)
Haemoglobin 200 g/l	2.39 (p < 0.05)	2.4 (1.2-5.1)		
Respiratory distress§	2.31 (p < 0.05)	2.6 (1.1-6.2)		

*Odds ratio is for each week shorter.

†Odds ratio is for each day in first 10

‡Odds ratio is for each day earlier.

§Requiring > 24 h ventilation

Logistic regression was used to adjust for any differences between groups in factors that have been associated previously with necrotising enterocolitis. The large differences between diet groups were seen even after adjustment for length of gestation, birthweight, sex, birth asphyxia, previous blood transfusions, use of theophylline and frusemide, polycythaemia, respiratory disease, duration of umbilical artery catheterisation, age at first enteral feed, rate of incrementation of early feed volumes, and maternal steroid treatment. One centre in study B had a slightly higher incidence of necrotising enterocolitis than the others. However, adjustment for any centre effects did not reduce the significance of the dietary findings.

In logistic regression models for all cases of necrotising enterocolitis and for confirmed cases (table IV), the independent variables were those of the factors above that were significantly related to the occurrence of necrotising enterocolitis. Length of gestation, duration of umbilical artery catheterisation, and age at first enteral feed were significant factors in both models, but in both the type of diet was the factor most strongly related to necrotising enterocolitis. For all cases of necrotising enterocolitis, a high haemoglobin concentration and respiratory distress were also significant factors.

TABLE V—RELATION BETWEEN FREQUENCY OF NECROTISING ENTEROCOLITIS AND GESTATION IN BABIES RECEIVING HUMAN MILK AND IN THOSE FED SOLELY ON FORMULA

—	All cases		Confirmed cases	
	Formula only	Human milk*	Formula only	Human milk*
Gestation				
25-27 wk	7/35 (20%)	13/83 (16%)	5/35 (14%)	7/83 (8%)
28-30 wk	7/83 (8%)	11/231 (5%)	5/83 (6%)	6/231 (3%)
31-33 wk	6/75 (8%)	3/263 (1%)	3/75 (4%)	1/263 (0.4%)
34-36 wk	4/43 (9%)	0/113	4/43 (9%)	0/113

*Breast milk alone or in combination with formula

The effect of length of gestation on the occurrence of necrotising enterocolitis differed significantly ($p < 0.02$) between infants fed formula only and those fed breast milk (either alone or in combination with formula). Thus, infants fed on formula only had little overall decline in the frequency of necrotising enterocolitis over the range of gestations studied (25-36 weeks) and no decline beyond 27 weeks. In contrast there was a sharp fall in the frequency of necrotising enterocolitis with length of gestation in infants receiving breast milk (table V); for example, by logistic regression the odds ratio for necrotising enterocolitis at 26 weeks compared with 32 weeks was 11.3 ($p < 0.001$). In the group of babies born at more than 30 weeks' gestation, there were only 3 (0.8%) cases among the 376 fed on human milk (1 confirmed) compared with 10 (8.5%) among the 118 fed on formula only (7 confirmed); the odds ratio was 11.5 (3.1-43; $p < 0.0001$) for all cases and 23.6 (2.9-194; $p < 0.0001$) for confirmed cases.

There was also interaction between diet and the day of first feeding ($p = 0.05$). In formula-fed babies delay in onset of the first feed was associated with a significantly lower incidence of necrotising enterocolitis, whereas in infants fed breast milk (alone or with formula) there was no such relation.

Discussion

During the past 15 years breast milk has been promoted for the feeding of preterm infants on the grounds that it may protect against necrotising enterocolitis. The few data to support this assertion are not, however, widely accepted.^{4,14,23} Indeed, a failure to establish clear benefits for breast milk in neonatal intensive care may be one of the reasons for a loss of enthusiasm for its use. In this large, prospective, multicentre study, the choice of early diet was the major factor associated with necrotising enterocolitis. Confirmed necrotising enterocolitis was 6 times as common in babies fed formula only than in those fed breast milk only; it was 10 times as common after adjustment for a wide range of factors associated previously with the disease. Furthermore, the risk of necrotising enterocolitis was 3.5 times higher in exclusively formula-fed infants than in those fed breast milk and formula combined, which suggests that breast milk can have an important protective role even when used as a supplement to formula feeding.

26% of our infants with confirmed necrotising enterocolitis died. Prognosis may be improving,²⁷ though an optimistic estimate for mortality in necrotising enterocolitis is 15-25%. If the frequency of cases in infants fed human milk either alone or in conjunction with formula is taken as a baseline, the excess frequency in babies who received no breast milk was 5-6 per 100 under 1850 g birthweight. Over the past 8 years the proportion of mothers in Cambridge providing any breast milk for their low birthweight infants has fallen from 75% to 55% (unpublished). Our enquiries suggest that in major parts of the UK the proportion providing any breast milk is likely to be lower. Furthermore, most British human milk banks have been closed. Probably about 50% of babies in neonatal intensive care receive no breast milk at all. If our data can be taken as representative and reflect causality, necrotising enterocolitis could occur in about 500 infants each year in the UK solely on account of exclusive formula feeding—more than 150 of them would require major abdominal surgery and about 100 would die.

The type of human milk given did not seem to affect the incidence of necrotising enterocolitis, despite theoretical predictions, from animal models, that only raw milk is

protective. We suggest, in the light of the finding that oral immunoglobulin in formula-fed babies was prophylactic,¹⁰ that breast milk may protect against necrotising enterocolitis by providing IgA in the gut lumen. Most IgA remains intact after milk pasteurisation.²⁸ Thus when mother's milk is unavailable, the use of pasteurised breast milk could have a valuable place in the initial establishment of enteral feeding in preterm infants.

An important factor in the widespread closure of milk banks has been concern over the possibility of transmission by way of breast milk of human immunodeficiency virus (HIV), though some investigators have suggested that routine pasteurisation of breast milk would destroy HIV,³¹ and HIV transmission has never been reported in a preterm infant fed pasteurised donor milk. This theoretical risk should be set against our finding of greater morbidity in premature babies who receive no human milk.

It is likely that a relation between diet and necrotising enterocolitis could have been missed in many previous studies that have had inadequate sample size and power, or inadequate control and monitoring of dietary intake. Our multicentre study was prospective, dietary assignment was strictly applied, and dietary management was carefully recorded and regulated; necrotising enterocolitis was a predetermined outcome response and extensive data were collected concomitantly that allowed adjustment for potential confounding factors. The diagnostic criteria we used for necrotising enterocolitis were those proposed after a large British multicentre study²⁶ rather than the similar criteria suggested by Bell²⁵ and most used in North America. Our cases all strictly met the criteria for grade 1 or 2 disease, and all the affected infants were treated with intravenous antibiotics and complete cessation of enteral feeding. Those confirmed by the most stringent criteria were presented separately, since they would be generally accepted as unequivocal cases.

As expected, length of gestation was a significant factor for necrotising enterocolitis. Nevertheless, over the whole range of gestation studied (25–36 weeks) the overall fall in confirmed necrotising enterocolitis risk was slightly smaller than the difference between groups fed exclusively on formula and on human milk. Although hypoxia and ischaemia have not been shown by some investigators to be risk factors for necrotising enterocolitis,^{1,2,7} we found, as others have,^{4,6} that respiratory distress, duration of use of an umbilical artery catheter (which might impede mesenteric flow, since most units used "high" catheter positioning), and polycythaemia (which could cause hyperviscosity and impair gut blood flow) were independently related to a higher incidence of the disease. These factors were not as strongly linked as diet.

In babies fed breast milk (alone or with formula) there was a sharp decline in incidence of necrotising enterocolitis with length of gestation; beyond 30 weeks' there was only 1 confirmed case among 376 babies. In contrast, there was no decline in necrotising enterocolitis incidence among formula-fed infants from 28 to 36 weeks' gestation; indeed beyond 30 weeks' gestation the overall incidence of confirmed disease was 20 times that in infants who received some breast milk. We suggest that early introduction of breast milk into the diets of preterm infants could make necrotising enterocolitis beyond 30 weeks' gestation a rarity.

In infants fed breast milk timing of the first feed was not related to frequency of necrotising enterocolitis, but in formula-fed infants, delay in starting feeds was associated

with a significant reduction—if enteral feeds were started on, for example day 9 rather than day 2, the risk of necrotising enterocolitis was reduced threefold. These data suggest that units offering only formula might reduce the frequency of necrotising enterocolitis by a more cautious approach to early feeding than would be needed if human milk was available.

In view of this strong link between diet and necrotising enterocolitis, feeding policies in neonatal units may need reappraisal. Active encouragement of mothers to provide at least some breast milk for their preterm infants, especially during the early weeks, seems justified. We recognise that such infants have increased nutritional requirements,^{29,30} but these can be met by concomitant use of preterm formulas and by human milk fortification. Furthermore, we consider it valuable for a major neonatal referral unit to support a human milk bank, despite the difficulties of donor screening for HIV.

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Direct diagnosis of carriers of Duchenne and Becker muscular dystrophy by amplification of lymphocyte RNA

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Rapid detection of deletion and duplication mutations that cause Duchenne and Becker muscular dystrophy was achieved in patients and carriers after amplification of small amounts of mRNA from peripheral blood lymphocytes. The entire coding region of the dystrophin mRNA was amplified in 10 sections by reverse transcription and nested polymerase chain reaction, and the products were directly visualised on acrylamide minigels with ethidium staining. Major structural gene mutations were identified by the appearance of a band of different size to that of the wild type. The altered band was readily detected in all patients and heterozygous relatives. This non-radioactive test of venous blood samples can be used for unambiguous and rapid identification of virtually all carriers of deletions or insertions within the dystrophin gene.

Lancet 1990; **336**: 1523-26.

Introduction

Duchenne and Becker muscular dystrophies (DMD, BMD) are X-linked diseases which together affect about 1 in 3000 live male births. The dystrophin gene is very large and has an unusually high mutation rate; mutations in unrelated families are likely to be of independent origin and a third of all cases arise from new mutations.¹ About two-thirds of all affected infants have no family history of DMD or BMD; for such sporadic cases segregation analysis is usually uninformative and the carrier risk for related women is difficult to estimate.^{2,3} Analysis of serum creatinine phosphokinase (CPK) concentrations⁴ relies on the heterozygote's phenotypic expression and can give variable results; in conjunction with family data these yield Bayesian probabilities rather than definitive diagnosis.

In 65% of patients with DMD or BMD the disease-causing mutation consists of deletion or duplication of exons within the gene.⁵ Such deletions are readily identified in patients by the absence of bands from Southern blots,^{6,7} or

by failure of amplification of individual reactions in multiplex polymerase chain reactions (PCRs).^{8,9} However, diagnosis is complicated in carrier women by the presence of the normal chromosome, which masks the result from the defective chromosome. Carrier diagnosis (and duplication detection in patients) therefore requires dosage analysis by Southern blot¹⁰ or PCR (Abbs S, et al, unpublished observations) in which the intensities of specific bands in different samples are compared. However, band intensity is dependent on various experimental factors, and carries a degree of uncertainty which many laboratories find unacceptable in clinical practice.

In 17% of patients with exon duplication or deletion the breakpoint is sufficiently close to a non-deleted exon that it lies within the restriction fragment detected by a cDNA probe on a Southern blot;⁵ such a band of altered mobility can be detected in carrier women. The frequency of detection of such diagnostic junction fragments—which provide unequivocal identification of the mutation in carriers—can be greatly increased by the use of pulsed-field gel electrophoresis.^{5,11} Such junction fragments may also be detected in mRNA: most deletion and duplication breakpoints lie within introns, which constitute over 99% of the dystrophin gene, so it is likely that transcription and transcript splicing are unaffected by the mutation. Thus a transcript from a defective gene would probably differ from the normal transcript only in that it bears a duplication or deletion of a number of exons. Amplification across the region of the mRNA which is duplicated or deleted should enable generation of a PCR product of anomalous size which is diagnostic of the presence of the defective gene.

Dystrophin mRNA is mainly expressed in muscle and brain, but Chelly et al¹² have shown that the dystrophin transcript is present in other tissues at about one copy per

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EXHIBIT “C”

An Exclusively Human Milk-Based Diet Is Associated with a Lower Rate of Necrotizing Enterocolitis than a Diet of Human Milk and Bovine Milk-Based Products

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Objective To evaluate the health benefits of an exclusively human milk-based diet compared with a diet of both human milk and bovine milk-based products in extremely premature infants.

Study design Infants fed their own mothers' milk were randomized to 1 of 3 study groups. Groups HM100 and HM40 received pasteurized donor human milk-based human milk fortifier when the enteral intake was 100 and 40 mL/kg/d, respectively, and both groups received pasteurized donor human milk if no mother's milk was available. Group BOV received bovine milk-based human milk fortifier when the enteral intake was 100 mL/kg/d and preterm formula if no mother's milk was available. Outcomes included duration of parenteral nutrition, morbidity, and growth.

Results The 3 groups (total n = 207 infants) had similar baseline demographic variables, duration of parenteral nutrition, rates of late-onset sepsis, and growth. The groups receiving an exclusively human milk diet had significantly lower rates of necrotizing enterocolitis (NEC; $P = .02$) and NEC requiring surgical intervention ($P = .007$).

Conclusions For extremely premature infants, an exclusively human milk-based diet is associated with significantly lower rates of NEC and surgical NEC when compared with a mother's milk-based diet that also includes bovine milk-based products. (*J Pediatr* 2010;156:562-7).

The health benefits of human milk for all infants, including those born extremely premature, have been increasingly recognized.¹ When compared with a diet of preterm formula, premature infants have improved feeding tolerance and a lower incidence of late-onset sepsis and necrotizing enterocolitis (NEC) when fed their mothers' milk.² It is a challenge for mothers of extremely premature infants, however, to provide sufficient milk to meet their infants' needs. In a recent study, only 30% of such mothers were able to supply 100% of their extremely premature infants' needs.³ Pasteurized donor human milk would be an attractive proxy for mother's own milk, and donor milk banks have made milk available.⁴ Indeed, a review of studies conducted in the 1980s, comparing donor human milk and formula, suggested that donor milk was associated with a significantly lower incidence of NEC.⁵ Those studies, however, did not include a large proportion of extremely premature infants, and their nutritional protocols did not evaluate human milk fortifiers (HMF) or contemporary preterm formula.

A randomized trial compared fortified pasteurized donor human milk with preterm formula, both used as supplements when mother's own milk was not available.³ That study did not find a protective effect of donor human milk on the combined incidence of late-onset sepsis and NEC but did note a significant

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BOV	Bovine milk-based human milk fortifier
HMF	Human milk fortifier
HM40	Human milk-based HMF added once feeding volume reached 40 mL/kg/day, and pasteurized donor milk used if no mother's own milk available.
HM100	Human milk-based HMF added once feeding volume reached 100 mL/kg/day and pasteurized donor milk used if no mother's own milk available.
NEC	Necrotizing enterocolitis
PN	Parenteral nutrition
SD	Standard deviation

protective effect of mother's own milk. The protocol in that study differed from previous studies in that the pasteurized donor human milk was fortified with bovine milk-based products, and some of the infants in the donor milk group were given preterm formula because of slower rates of growth. Thus no contemporary trial has investigated the effects of an exclusively human milk diet in extremely premature infants.

The technology now exists to collect, pasteurize, and process large quantities of screened donor human milk, labeled with its basic nutrient contents, and prepared as either a HMF or a donor milk alternative to mother's own milk.⁶ This technology has prompted a randomized controlled trial in extremely premature infants to evaluate an exclusive human milk-based diet (that includes a human milk-based HMF and donor human milk if no mother's milk is available) compared with the usual feeding protocol comprising a mother's milk diet (that includes a bovine milk-based HMF and preterm formula if no mother's milk is available). We hypothesized that the health benefits (reduced duration of parenteral nutrition [PN], late-onset sepsis, and NEC) of an exclusively human milk-based diet would exceed those of the usual diet containing bovine milk-based products without detrimental effects on growth.

Methods

Infants were recruited from 12 neonatal intensive care units, 11 in the United States and 1 in Austria. Eligibility criteria were as follow: birth weight 500 to 1250 g, intention to receive mother's milk, and ability to adhere to a feeding protocol on the basis of the use of mother's own milk, initiation of enteral feeding before 21 days after birth, and initiation of PN within 48 hours of birth. Infants were excluded if there were major congenital malformations or a high likelihood of transfer to a non-study institution during the study period.

Randomization was performed in blocks of 4 on strata defined by birth weight (500 to 750 g, 751 to 1000 g, and 1001 to 1250 g), and whether the infant was appropriate- or small-for-gestational-age (defined as 2 standard deviations below the mean weight for gestational age on the basis of intrauterine growth charts⁷). Separate block randomization schemes were prepared for each of the strata and performed centrally. The investigators were not aware of the block size. The need to ensure proper handling of mother's own milk precluded true blinding of the infants' caregivers.

Sample size calculation was based on the primary outcome of duration of PN, a surrogate of feeding tolerance and neonatal morbidity. The mean duration of PN in extremely premature infants fed their mother's fortified milk was 18 ± 11 days (Meier and Blanco, personal communication). To demonstrate a 40% reduction in PN days in either study group, a sample size of 62 infants per group was needed for a 2-sided alpha error of 2.5% and power of 90%. To account for 2 interim analyses by the independent Data Safety Monitoring Board, and an estimated proportion of protocol non-

adherence of 5%, the final sample was 69 infants per group. The study was approved by the institutional review boards of each center and written informed consent was obtained from the parents or legal guardians of all subjects before enrollment. Registered with [Clinicaltrials.gov](https://clinicaltrials.gov) reg. # NCT00506584.

Infants were enrolled if their mothers intended to provide their own milk. When enteral nutrition was initiated, all study infants received their own mothers' milk but differed, as randomized, by the type of HMF they received and the type of milk they were given if no mother's own milk was available. Groups HM100 and HM40 received pasteurized donor human milk-based HMF (Prolacta+ H²MF; Prolacta Bioscience, Monrovia, California) when the enteral intake was 100 mL/kg/d and 40 mL/kg/d, respectively, and both groups received pasteurized and standardized 20 kcal/oz donor human milk (Neo20 Prolacta Bioscience) if no mother's milk was available. Group BOV received the usual feeding protocol of bovine milk-based HMF when the enteral intake was 100 mL/kg/d and preterm formula if no mother's own milk was available.

The duration of study participation was the earliest of the following milestones: 91 days of age, discharge from hospital, or attainment of 50% oral feedings (ie, 4 complete oral feedings per day). PN was initiated within 48 hours after birth. Trophic feedings were initiated 1 to 4 days after birth and were continued at 10 to 20 mL/kg/d as tolerated for up to 5 days. Subsequently, milk intake was increased by 10 to 20 mL/kg/d. Donor human milk-based HMF was added in the HM40 group when milk intake reached 40 mL/kg/d and in the HM100 group at 100 mL/kg/day. Bovine milk-based HMF (Enfamil HMF; Mead Johnson, Evansville, Indiana; or Similac HMF; Abbott Laboratories, Columbus, Ohio) was added in the BOV group when milk intake reached 100 mL/kg/d. After the HMF was added, milk intake was increased daily by 10 to 20 mL/kg to a maximum of 160 mL/kg/d. The nutritional content of the fortified milks used in the study is described in [Table I](#) (available at www.jpeds.com).

Daily body weight and weekly recumbent length and head circumference were recorded. Bronchopulmonary dysplasia was defined as the use of supplemental oxygen at 36 weeks postmenstrual age. Late-onset sepsis was defined as clinical signs and symptoms consistent with sepsis occurring more than 5 days after birth in association with the isolation of a causative organism from a blood culture.³ In cases of coagulase-negative *Staphylococcus*, at least 2 separate positive cultures were required. NEC was defined as Bell Stage II disease or greater, and abdominal radiographs were read by radiologists unaware of study group assignment.⁸ At the conclusion of the study, all cases of NEC were reviewed in a blinded fashion by a panel of 8 of the study investigators. Feeding intolerance was defined as gastric residuals greater than 50% of the prior feeding or more than 2 mL/kg, bile- or blood-stained gastric residuals, emesis, abdominal distention or tenderness, changes in stool pattern or consistency, presence of blood in the stool. Feeding intolerance was quantitated by

the number of days that feedings were withheld for ≥ 12 hours.

Statistical Analyses

The 3 study groups were compared by use of an intent-to-treat paradigm, any randomized infant remained in their group for the final analyses. Kaplan-Meier⁹ estimates for the distribution of PN days were compared among study groups with the log-rank test. The Wilcoxon rank-sum test was used for 2-way comparisons. Three-way comparisons used either the 1-way analysis of variance for normally distributed data or the Kruskal-Wallis test for nonnormal data. Categorical data were compared by use of the χ^2 test with the *P* value determined by an exact procedure (StatXact 7; Cytel Software Corporation, Cambridge, Massachusetts).

Results

During the 14 months of the study, 334 infants were screened, and 207 were enrolled (Figure 1). The baseline characteristics of infants among the 3 study groups were similar (Table II). The ages of attainment of first enteral feeding (15, 11, and 16 days) and full (140 mL/kg/d) enteral feeding (21, 23, and 22 days) were similar among HM100, HM40, and BOV groups, respectively. There were no significant differences among study groups for the duration of PN, length of hospital stay, late-onset sepsis, or growth (Table III). The number of infants below the third percentile⁷ at birth and at discharge was similar among groups.

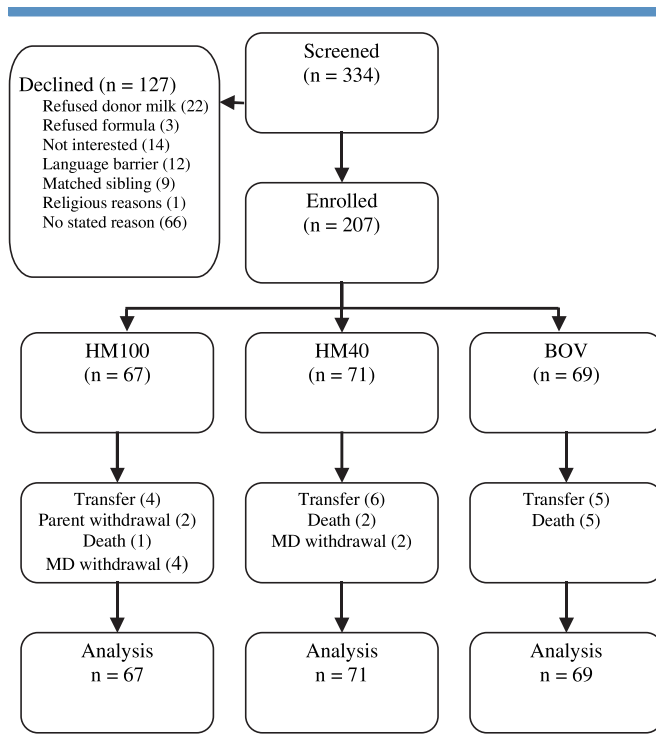


Figure 1. Distribution of study subjects.

Because there were no differences between HM100 and HM40, the exclusive HM group (HM100 + HM40) was compared with the BOV group. This analysis revealed similarities in baseline data and most outcomes, with the exception that there were fewer black infants in the BOV group compared with the combined HM100 + HM40 groups, 14% versus 27%, *P* = .046, and that the rate of weight gain was greater in the BOV group compared with the HM100 + HM40 groups, 16.0 ± 7.8 vs 14.3 ± 3.8 g/kg/d, *P* = .051.

Significant differences, however, were observed among study groups for the incidence of NEC (Figure 2). When compared with the BOV group, there were fewer cases of NEC in the HM100 and HM40 groups and the combined exclusive human milk-based diet groups (HM100 + HM40). A significant difference among groups was observed for the combined outcome of NEC or death in HM100 (6%), HM40 (8.5%), and BOV (20%), respectively, *P* = .02. The onset of NEC was similar among groups, 35 ± 18 , 41 ± 18 , 28 ± 12 postnatal days and 31 ± 1 , 32 ± 3 , and 31 ± 2 weeks post-menstrual age, in Groups HM100, HM40, and BOV, respectively. The number of cases of NEC requiring surgical intervention was significantly lower in the HM100 and HM40 groups compared with BOV group (Figure 2). All cases of surgical NEC occurred in infants who received bovine milk-based milk products (either HMF or preterm formula) at some time before the onset of NEC (Table IV; available at www.jpeds.com). Seven of these infants were randomized to the BOV group, but 2 of these infants were in the HM100/HM40 groups who had received bovine milk-based HMF or formula in violation of the protocol.

The 19 cases of NEC were distributed as 1 to 4 cases per site among 9 of the study sites. When rates of NEC were tabulated for only infants who completed the study without any protocol violations, the same distribution of cases was observed: 1.7%, 3.2%, and 15.3%, in HM100, HM40, and BOV groups, respectively; *P* = .006. A multivariate logistic regression that controlled for confounding variables known to affect the incidence of NEC (5-minute APGAR score, quantity of mother's own milk received, gestational age, receipt of prenatal and postnatal steroids, black race, bronchopulmonary dysplasia^{10,11}) found an odds ratio for NEC with an exclusive human milk diet of 0.23 (95% confidence interval = 0.08, 0.66), *P* = .007, or a 77% reduction in the odds of developing NEC while receiving an exclusive human milk diet. None of the other variables reached statistical significance.

Infants in all 3 groups received a large volume and proportion of their enteral intake as their own mother's milk (Table III). The BOV group received significantly more own mother's milk because the fortifier was a powdered preparation whereas a liquid fortification regimen was used in the exclusive human milk groups.

Discussion

We conducted a randomized controlled multicenter trial to evaluate the potential health benefits of an exclusively human milk diet in extremely premature infants, 500 to

Table II. Characteristics of study infants

Parameter	HM100 (n = 67)	HM40 (n = 71)	BOV (n = 69)	P value
Birth weight, g	945 ± 202*	909 ± 193	922 ± 197	.56
Gestational age, wk	27.2 ± 2.2	27.1 ± 2.3	27.3 ± 2.0	.93
Male/Female, n (%)	32/35 (48/52)	25/46 (35/65)	36/33 (52/48)	.11
Small-for-gestational age, n (%)	6 (9)	6 (8)	8 (12)	.80
APGAR Score < 6, n (%)	9 (13)	4 (6)	8 (12)	.28
Black race n (%)	20 (30)	17 (24)	10 (14)	.10
Antenatal steroids, n (%)	56 (83)	51 (72)	53 (77)	.26
Mechanical ventilation at study entry, n (%)	49 (73)	56 (79)	53 (77)	.73

*Mean ± SD.

1250 g birth weight. This study was unique for its use of human milk–based human milk fortification. We were unable to demonstrate significant differences among the groups for the primary health outcome, PN days, a surrogate measure for feeding tolerance and early morbidity. Furthermore, we did not find significant differences in several other clinical outcomes. We speculate that the lack of differences is a direct result of the overall high intake of mother’s own milk, which comprised more than 70% of enteral nutrition across all study groups. The high human milk intake reflects contemporary trends of improved lactation support and caregiver awareness and is consistent with the impact of human milk studies on this measure.^{2,12,13}

Surprisingly, the rates of NEC and NEC requiring surgery were markedly lower in the groups fed human milk exclusively (HM100 and HM40) compared with the BOV group. We found a reduction in NEC of 50% and surgical NEC of almost 90% in infants fed an exclusive human milk diet compared with a diet containing bovine milk–based products. We estimate that the number of infants needed to treat with an exclusively human milk–based diet to prevent 1 case of NEC is 10. The number needed to treat to prevent 1 case of surgical NEC or death is 8. No other intervention has been shown to have such a marked effect on the incidence of NEC.¹⁴ The mean incidence of NEC in the Vermont-Oxford Database (2007), approximately 7% to 10%, is in the range observed in this study. A 50% reduction in NEC would

prevent between 1300 to 1850 cases annually, with each case leading to a high risk of death and long-term morbidity, and a hospitalization cost estimated at \$138 000 to \$238 000 per case.^{4,15}

The lower incidence and severity of NEC in infants fed an exclusively human milk diet seen in our study are consistent with earlier reports. In 1990, Lucas and Cole¹⁶ reported a reduction in the incidence of NEC among infants who received only human milk when compared with infants who received all bovine milk–based formula. Those infants who received a mixture of formula and human milk had an intermediate level of protection. Lucas¹⁷ also reported a lower incidence of surgical NEC in infants fed unfortified compared with bovine milk–based fortified human milk. Lastly, 3 published meta-analyses concluded that donor human milk feeding was associated with less NEC.^{5,18,19}

Our data contrast those reported in 2005,³ which failed to find a protective effect of donor human milk on the combined incidence of sepsis and NEC, but reported that mother’s own milk with bovine milk–based HMF was protective. That study, which also was analyzed on the intent-to-treat principle, included infants randomized to receive donor milk who were given formula because of poor growth, and all infants received a bovine milk–based fortifier. In 1984 Narayanan²⁰ reported a greater number of infections in premature infants fed pasteurized donor milk when they were also exposed to bovine milk-based formula. She concluded that pasteurized

Table III. Study outcomes

Outcome	HM100 (n = 67)	HM40 (n = 71)	BOV (n = 69)	P value
Parenteral nutrition, days	20* (14, 35)	20 (12, 33)	22 (14, 34)	.71
Length of stay, days	74 (61, 107)	79 (64, 110)	78 (67, 99)	.90
Mother’s own milk, mL per study	4048 (841, 7479)	4544 (627, 8012)	5676 (1064, 8309)	.71
Mother’s own milk, % enteral intake	73 (16, 82)	70 (18, 80)	82 (38, 100)	.002
Late-onset sepsis (LOS), n (%)	19 (28)	15 (21)	13 (19)	.39
LOS and/or NEC, n (%)	22 (33)	20 (28)	21 (30)	.84
Retinopathy of prematurity, n (%)	31 (46)	25 (35)	27 (39)	.41
Ventilator, days	25 (6, 54)	25 (12, 50)	34 (10, 58)	.54
Oxygen therapy, days	41 (24, 63)	48 (12, 78)	45 (19, 74)	.92
Central line, days	21 (15, 36)	22 (14, 30)	22 (16, 30)	.82
Bronchopulmonary dysplasia, n (%)	22 (33)	26 (37)	27 (39)	.74
Weight gain, (g/kg/day)	14.2 (11.9, 15.8)	14.2 (12.3, 16.3)	15.1 (12.8, 17.0)	.13
Length increment, (cm/wk)	0.86 (0.72, 1.08)	0.88 (0.70, 1.03)	0.94 (0.72, 1.16)	.35
Head circumference increment, cm/wk	0.76 (0.62, 0.85)	0.75 (0.61, 0.88)	0.75 (0.62, 0.86)	.99

*Median (25th, 75th percentile).

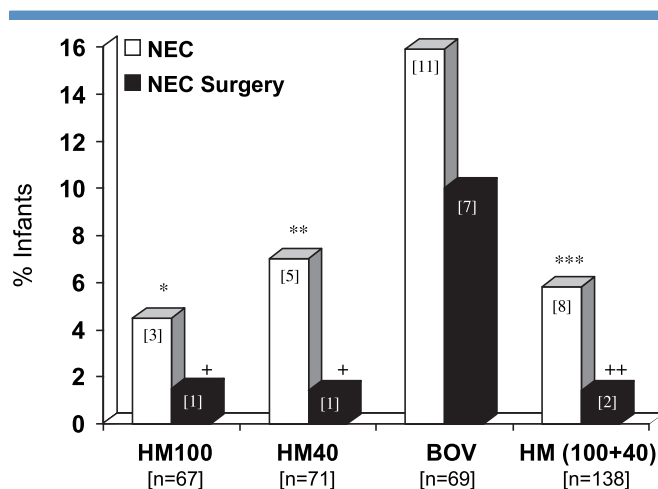


Figure 2. NEC and NEC surgery in study infants. There were significant differences in NEC among the 3 groups ($P = .05$), $*P = .04$ vs BOV, $**P = .09$ vs BOV, $***P = .02$ vs BOV. There were significant differences in NEC requiring surgical intervention among the 3 groups ($P = .02$), $^{\dagger}P = .03$ vs BOV, $^{\dagger\dagger}P = .007$ vs BOV. [] refers to number of infants.

donor milk was effective only if it was fed as the total source of enteral nutrition.²¹ These data suggest that exclusive human milk diets may exert protective, rather than threshold, effects with respect to NEC. The feeding of a species-specific diet may be important for this protection. However, we cannot exclude the possibility that the protective effect primarily was due to the avoidance of non human milk-based protein. Indeed, an animal model for NEC requires intraluminal bovine casein to produce the enterocolitis.²²

This study also introduced an earlier fortification strategy with human milk-based human milk fortifier (HM40) to assess, secondarily, if such early fortification could be tolerated without introducing added morbidity. The 71 infants receiving the early fortification strategy appeared to tolerate the feeding well and did not differ significantly in feeding tolerance or other outcomes from the HM100 group. These are encouraging data that suggest the possibility of earlier introduction of human milk-based fortification compared with the usual practice of adding HMF at an enteral intake of 100 mL/kg/d.

The strengths of this study include a randomization and stratification scheme that achieved a balance of patient characteristics across the study groups and good adherence to the protocol as evidenced by a very small number of protocol violations. The control group correctly mimicked how extremely premature infants are fed, by use of combinations of mother's own milk and bovine-based products (HMF and formula). Limitations include the lack of complete blinding, which was not possible because of the obvious physical differences in human milk and formula and the limited power to look at subgroups, including those defined by sex and birth weight.

We conclude that for extremely premature infants, an exclusively human milk-based diet is associated with a significant reduction in the rates of NEC and surgical NEC

compared with dietary exposure to bovine milk-based products. The similarities in other outcomes and the lower rate of NEC among study groups add support to the use of an exclusively human milk-based diet. The newer technology that enables an exclusively human milk diet with human milk-based fortification is now available to assist the ongoing efforts of neonatologists in their advocacy of human milk to reduce neonatal morbidity rates. ■

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Table I. Computed energy and macronutrient contents of milks (per dL)

Component	Mother's own milk*	Mother's own milk fortified with Prolacta fortifier†	Mother's own milk fortified with Similac HMF*	Mother's own milk fortified with Enfamil HMF‡
Energy (kcal)	67	83	79	81
Protein (g)	1.4	2.3	2.3	2.5
Carbohydrate (g)	6.6	7.3	8.2	7
Fat (g)	3.9	4.9	4.1	4.9
Calcium (mg)	25	110	138	115
Phosphorus (mg)	13	59	78	63
Osmolality§ (mOsm/kg H ₂ O)	290	< 360	est 385	325

*Abbott Nutrition, Columbus, Ohio. Product Description. 2009.

†Prolacta Bioscience, Monrovia, California. Product Description. 2009.

‡Mead Johnson Nutritionals, Evansville, Indiana. Product Description. 2009.

§NEOFAX 2009. Thomson Reuters, Montvale, New Jersey, pages 321-4.

Table IV. Characteristics of the NEC cases

Study group	Birth weight (g)	Gestational age (wk)	First day enteral feeding (day)	First day bovine milk-based HMF or formula (day)	First day human milk-based fortifier (day)	NEC onset (day)	Comment
HM100	720	25	5		32	35	
HM100	560	25	4	47*	20	53	NEC surgery
HM100	1105	28	3		9	18	
HM40	530	22	3		26	58	
HM40	740	25	9		17	38	
HM40	990	27	1	1*	7	22	NEC surgery†
HM40	785	28	1	77	3	60	
HM40	970	29	2	2*	5	25	
BOV	670	25	18	24		46	NEC surgery
BOV	690	25	1	1		17	NEC surgery
BOV	1170	26	1	11		25	NEC surgery
BOV	870	26	10	45	12‡	51	NEC surgery†
BOV	1136	27	1	13		18	NEC surgery
BOV	775	27	3	11		16	NEC surgery†
BOV	1120	28	5	16		38	
BOV	840	28	8	10		29	
BOV	1230	29	2	2		23	
BOV	1100	29	3	30		14	
BOV	817	29	2	12		26	NEC surgery

*Erroneously received formula or bovine milk-based HMF in violation of protocol.

†Died.

‡Erroneously received human milk-based HMF in violation of protocol.

EXHIBIT A-32



IN THE COURT OF COMMON PLEAS OF PHILADELPHIA COUNTY
FIRST JUDICIAL DISTRICT OF PENNSYLVANIA
TRIAL DIVISION – CIVIL

STILLS ETAL

VS

***MEAD JOHNSON NUTRITION COMPANY
ETAL***

March Term 2022

No. 02617

***CASE MANAGEMENT ORDER
COMPLEX TRACK***

AND NOW, 20-JUN-2023 , it is Ordered that:

1. The case management and time standards adopted for complex track cases shall be applicable to this case and are hereby incorporated into this Order.
2. All ***discovery*** on the above matter shall be completed not later than ***02-OCT-2023***.
3. ***Plaintiff*** shall identify and submit ***curriculum vitae and expert reports*** of all expert witnesses intended to testify at trial to all other parties not later than ***06-NOV-2023***.
4. ***Defendant and any additional defendants*** shall identify and submit curriculum vitae and expert reports of all expert witnesses intended to testify at trial not later than ***04-DEC-2023***.
5. All ***pre-trial motions*** shall be filed not later than ***04-DEC-2023***.
6. A ***settlement conference*** may be scheduled at any time after ***02-JAN-2024***. Prior to the settlement conference all counsel shall serve all opposing counsel and file a settlement memorandum containing the following:
 - (a). A concise summary of the nature of the case if plaintiff or of the defense if defendant or additional defendant;
 - (b). A statement by the plaintiff or all damages accumulated, including an itemization of injuries and all special damages claimed by categories and amount;
 - (c). Defendant shall identify all applicable insurance carriers, together with applicable limits of liability.
7. A ***pre-trial conference*** will be scheduled any time after ***04-MAR-2024***. Fifteen days prior to pre-trial conference, all counsel shall serve all opposing counsel and file a pre-trial memorandum containing the following:

CMOIS-Stills Etal Vs Mead Joh



22030261700040

- (a). A concise summary of the nature of the case if plaintiff or the defense if defendant or additional defendant;
 - (b). A list of all witnesses who may be called to testify at trial by name and address. Counsel should expect witnesses not listed to be precluded from testifying at trial;
 - (c). A list of all exhibits the party intends to offer into evidence. All exhibits shall be pre-numbered and shall be exchanged among counsel prior to the conference. Counsel should expect any exhibit not listed to be precluded at trial;
 - (d). Plaintiff shall list an itemization of injuries or damages sustained together with all special damages claimed by category and amount. This list shall include as appropriate, computations of all past lost earnings and future lost earning capacity or medical expenses together with any other unliquidated damages claimed; and
 - (e). Defendant shall state its position regarding damages and shall identify all applicable insurance carriers, together with applicable limits of liability;
 - (f). Each counsel shall provide an estimate of the anticipated length of trial.
8. ***It is expected that the case will be ready for trial 01-APR-2024***, and counsel should anticipate trial to begin expeditiously thereafter.
9. All counsel are under a continuing obligation and are hereby ordered to serve a copy of this order upon all unrepresented parties and upon all counsel entering an appearance subsequent to the entry of this Order.

BY THE COURT:

LINDA CARPENTER, J.
TEAM LEADER

EXHIBIT A-33

KLINE & SPECTER, P.C.

THOMAS R. KLINE, ESQUIRE

Attorney I.D. No. 28895

TOBIAS MILLROOD, ESQUIRE

Attorney I.D. No. 77764

ELIZABETH CRAWFORD, ESQUIRE

Attorney I.D. No. 313702

MELISSA MERK, ESQUIRE

Attorney I.D. No. 90363

TIMOTHY A. BURKE, ESQUIRE

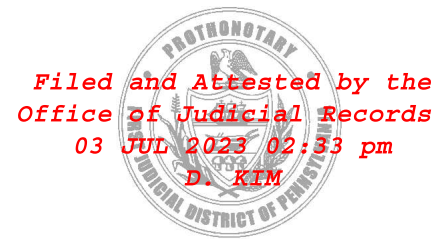
Attorney I.D. No. 320927

1525 Locust Street, 19th Floor

Philadelphia, PA 19102

(215) 772-1000/(215) 772-1359 fax.

Attorney for Plaintiffs



IN THE COURT OF COMMON PLEAS OF PHILADELPHIA COUNTY
FIRST JUDICIAL DISTRICT OF PENNSYLVANIA
TRIAL DIVISION - CIVIL

TERRAINE ABDULLAH, et al., Plaintiff,	:	
v.	:	MARCH TERM, 2022
MEAD JOHNSON & COMPANY, LLC, et al.,	:	No. 220302583
Defendants.	:	
HOLLI CARTER, et al., Plaintiff,	:	
v.	:	MARCH TERM, 2022
MEAD JOHNSON & COMPANY, LLC, et al.,	:	No. 220302588
Defendants.	:	
SHONDERA DRAYTON, et al., Plaintiff,	:	
v.	:	MARCH TERM, 2022
MEAD JOHNSON & COMPANY, LLC, et al.,	:	No. 220302594
Defendants.	:	
BRANDY GOODMOND, et al., Plaintiff,	:	
v.	:	APRIL TERM, 2022
MEAD JOHNSON & COMPANY, LLC, et al.,	:	No. 220400208
Defendants.	:	

BRANDY GOODMOND, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	: : : : :	APRIL TERM, 2022 No. 220400212
TONYA GRAY, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	: : : : :	APRIL TERM, 2022 No. 220400216
JANEE HENDERSON, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	: : : : :	APRIL TERM, 2022 No. 220400127
DELQUAN HINES, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	: : : : :	APRIL TERM, 2022 No. 220400136
SHEMIKA JOHNSON, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	: : : : :	APRIL TERM, 2022 No. 220400162
KRISTEN KAJUFFA, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	: : : : :	MARCH TERM, 2022 No. 220302978
NAFEESA MAYS, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	: : : : :	MARCH TERM, 2022 No. 220302963
CATHERINE McMILLIAN, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	: : : : :	APRIL TERM, 2022 No. 220400140
DAMEKA MOMENT, et al., Plaintiff,	: :	APRIL TERM, 2022

v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	: : :	No. 220400142
ERICA PADILLA, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	: : : : :	MARCH TERM, 2022 No. 220302969
NYDIA PARKER, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	: : : : :	MARCH TERM, 2022 No. 220302983
ALEXANDRIA ROSS, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	: : : : :	MARCH TERM, 2022 No. 220302981
LOREN SANDERS, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	: : : : :	APRIL TERM, 2022 No. 220400153
SAMAYA SHORT, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	: : : : :	APRIL TERM, 2022 No. 220400159
ALICE STILLS, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	: : : : :	MARCH TERM, 2022 No. 220302617
CHRISTINA TAYLOR, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	: : : : :	MARCH TERM, 2022 No. 220302606
NATISHA THOMAS, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al.,	: : : :	MARCH TERM, 2022 No. 220400158

Defendants.	:	
TRINA WALKER-SAVAGE and CLIFTON	:	
ISAAH SAVAGE, JR., et al.,	:	MARCH TERM, 2022
Plaintiff,	:	No. 220400156
v.	:	
MEAD JOHNSON & COMPANY, LLC, et al.,	:	
Defendants.	:	
JEANNATE WATSON, et al.,	:	
Plaintiff,	:	MARCH TERM, 2022
v.	:	No. 220302967
MEAD JOHNSON & COMPANY, LLC, et al.,	:	
Defendants.	:	
ROBERT WHITFIELD, et al.,	:	
Plaintiff,	:	APRIL TERM, 2022
v.	:	No. 220400145
MEAD JOHNSON & COMPANY, LLC, et al.,	:	
Defendants.	:	
GINA WIEGER, et al.,	:	
Plaintiff,	:	MARCH TERM, 2022
v.	:	No. 220302614
MEAD JOHNSON & COMPANY, LLC, et al.,	:	
Defendants.	:	
GINA WIEGER, et al.,	:	
Plaintiff,	:	MARCH TERM, 2022
v.	:	No. 220302601
MEAD JOHNSON & COMPANY, LLC, et al.,	:	
Defendants.	:	
SHANITA WIGGINS, et al.,	:	
Plaintiff,	:	MARCH TERM, 2022
v.	:	No. 220302986
MEAD JOHNSON & COMPANY, LLC, et al.,	:	
Defendants.	:	
MELVENIA WILLIAMS, et al.,	:	
Plaintiff,	:	APRIL TERM, 2022
v.	:	No. 220400141
MEAD JOHNSON & COMPANY, LLC, et al.,	:	
Defendants.	:	
IVYANN WITHERSPOON, et al.,	:	
Plaintiff,	:	APRIL TERM, 2022
v.	:	No. 220400138
MEAD JOHNSON & COMPANY, LLC, et al.,	:	
Defendants.	:	

STIPULATION

TO THE Prothonotary:

The parties stipulate that plaintiffs have until August 7, 2023 to reply to defendants' Preliminary Objections in the above-captioned matters, with defendants' reply briefs to be filed by August 17th.

July 3, 2023

Respectfully submitted,

<p>TROUTMAN PEPPER HAMILTON SANDERS LLP</p> <p><u>/s/ Ronnie E. Fuchs</u> Sean P. Fahey, Esquire 3000 Two Logan Square Philadelphia, PA 19103 Tel: (215) 981-4296</p> <p>Ronni E. Fuchs 301 Carnegie Center, Suite 400 Princeton, NJ 08540 Tel: (609) 951-4183</p> <p>Kimberly A. Brown JONES DAY 500 Grant Street, Suite 4500 Pittsburgh, PA 15219 Tel: (412) 394-7995</p> <p><i>Attorneys for Defendant Abbott Laboratories</i></p>	<p>KLINE & SPECTER, P.C.</p> <p><u>/s/ Timothy A. Burke</u> Thomas R. Kline, Esquire Tobias Millrood, Esquire Elizabeth Crawford, Esquire Melissa Merk, Esquire Timothy A. Burke, Esquire 1525 Locust Street Philadelphia, PA 19102 1525 Locust Street Philadelphia, PA 19102 Tel: (215) 772-1000</p> <p><i>Attorneys for Plaintiff</i></p>
<p>BURNS WHITE LLC</p> <p><u>/s/ Richard S. Margulies</u> James A. Young, Esquire Richard S. Margulies, Esquire Susan R. Engle, Esquire Attorney ID Nos. 00213/62306/81671 1880 John F. Kennedy Boulevard, 10th FL</p>	<p>TUCKER LAW GROUP, LLC</p> <p><u>/s/ Kenneth A. Murphy</u> Kenneth A. Murphy, Esquire Heather R. Olson, Esquire Ten Penn Center 1801 Market Street, Suite 2500 Philadelphia, PA 19103</p>

<p>Philadelphia, PA 19103 Tel: (215) 587-1625</p> <p><i>Attorneys for Defendant University of Pennsylvania Hospital of the University of Pennsylvania Health System d/b/a Pennsylvania Hospital and University of Pennsylvania Hospital of the University of Pennsylvania Health System d/b/a Penn Medicine</i></p>	<p>WELSH & RECKER, P.C. Catherine M. Recker Amy B. Carver Richard D. Walk, III 306 Walnut Street Philadelphia, PA 19106 Tel: (215) 972-6430</p> <p><i>Attorneys for Defendant Mead Johnson & Company LLC and Mead Johnson Nutrition Company</i></p>
<p>BURNS WHITE LLC</p> <p><u>/s/ Richard S. Margulies</u> James A. Young, Esquire Richard S. Margulies, Esquire Susan R. Engle, Esquire Attorney ID Nos. 00213/62306/81671 1880 John F. Kennedy Boulevard, 10th FL Philadelphia, PA 19103 Tel: (215) 587-1625</p> <p><i>Attorneys for Defendant, Temple University Health System, Inc., d/b/a Temple University Hospital</i></p>	

CERTIFICATE OF SERVICE

I hereby certify that on July 3, 2023, I caused a true and correct copy of the foregoing document to be served by electronic filing to all counsel of record.

Dated: July 3, 2023

/s/ Timothy A. Burke
Timothy A. Burke

EXHIBIT A-34

PHILADELPHIA COURT OF COMMON PLEAS PETITION/MOTION COVER SHEET

FOR COURT USE ONLY	
ASSIGNED TO JUDGE:	ANSWER/RESPONSE DATE: 08/07/2023
Do not send Judge courtesy copy of Petition/Motion/Answer/Response. Status may be obtained online at http://courts.phila.gov	

CONTROL NUMBER:

23072525

**(RESPONDING PARTIES MUST INCLUDE THIS
NUMBER ON ALL FILINGS)**

March, 2022
Month Term, Year
No. 02617

STILLS ETAL VS MEAD JOHNSON NUTRITION
COMPANY ETAL

Name of Filing Party:

ALICE STILLS-PLF
M E-PMNR

INDICATE NATURE OF DOCUMENT FILED:

☐ Petition (*Attach Rule to Show Cause*) ☒ Motion
☐ Answer to Petition ☐ Response to Motion

Has another petition/motion been decided in this case? ☒ Yes ☐ NoIs another petition/motion pending? ☒ Yes ☐ No

If the answer to either question is yes, you must identify the judge(s):
CARPENTER

TYPE OF PETITION/MOTION (see list on reverse side) MOT-FOR ADMISSION PRO HAC VICE		PETITION/MOTION CODE (see list on reverse side) MTPHV
ANSWER / RESPONSE FILED TO (Please insert the title of the corresponding petition/motion to which you are responding):		
I. CASE PROGRAM DAY FORWARD/MAJOR JURY PROGRAM Name of Judicial Team Leader: <u>JUDGE LINDA CARPENTER</u> Applicable Petition/Motion Deadline: <u>07/06/2023</u> Has deadline been previously extended by the Court: <u>NO</u>	II. PARTIES (<i>required for proof of service</i>) (Name, address and telephone number of all counsel of record and unrepresented parties. Attach a stamped addressed envelope for each attorney of record and unrepresented party.) JAMES A YOUNG BURNS WHITE LLC 1880 JOHN F. KENNEDY BOULEVARD 10TH FLOOR , PHILADELPHIA PA 19103 SEAN P FAHEY TROUTMAN PEPPER 3000 TWO LOGAN SQ 18TH AND ARCH STREETS , PHILADELPHIA PA 19103-2799 JOSEPH E ONEIL CAMPBELL CONROY & ONEIL 1205 WESTLAKES DR SUITE 330 , BERWYN PA 19312 MARQUES HILLMAN RICHESON JONES DAY 901 LAKESINDE AVENUE NORTH POINT , CLEVELAND OH 44114 THOMAS R KLINE KLINE & SPECTER 1525 LOCUST ST., 19TH	
III. OTHER		

By filing this document and signing below, the moving party certifies that this motion, petition, answer or response along with all documents filed, will be served upon all counsel and unrepresented parties as required by rules of Court (see PA. R.C.P. 206.6, Note to 208.2(a), and 440). Furthermore, moving party verifies that the answers made herein are true and correct and understands that sanctions may be imposed for inaccurate or incomplete answers.

(Attorney Signature/Unrepresented Party)

July 14, 2023
(Date)

TOBIAS L. MILLROOD
(Print Name) (Attorney I.D. No.)

**The Petition, Motion and Answer or Response, if any, will be forwarded to the Court after the Answer/Response Date.
No extension of the Answer/Response Date will be granted even if the parties so stipulate.**

FL. , PHILADELPHIA PA 19102
KENNETH A MURPHY
TUCKER LAW GROUP, LLC 1801 MARKET
STREET SUITE 2500 , PHILADELPHIA PA
19103-6996

FILED
14 JUL 2023 04:59 pm
Civil Administration
P. CHROY

KLINE AND SPECTER, P.C.

By: TOBIAS L. MILLROOD, ESQUIRE
ELIZABETH A. CRAWFORD, ESQUIRE
JOHN P. O'NEILL, ESQUIRE

Attorney I.D. No. 77764 / 313702 / 205677

1525 Locust Street

Philadelphia, PA 19102

(215) 772-1000 phone

(215) 792-5519 fax

Tobi.Millrood@klinespecter.com

Elizabeth.Crawford@Klinespecter.com

Jack.Oneill@klinespecter.com

ALICE STILLs, on her own behalf and as Parent
and Natural Guardian of M.E., a Minor,

Plaintiff,

v.

MEAD JOHNSON & COMPANY, LLC, MEAD
JOHNSON NUTRITION COMPANY, ABBOTT
LABORATORIES, THE PENNSYLVANIA HOSPITAL
OF THE UNIVERSITY OF PENNSYLVANIA HEALTH
SYSTEM d/b/a PENNSYLVANIA HOSPITAL, and
THE TRUSTEES OF THE UNIVERSITY OF
PENNSYLVANIA d/b/a PENN MEDICINE,

Defendants.

**IN THE COURT OF COMMON PLEAS
PHILADELPHIA COUNTY**

CIVIL TRIAL DIVISION

**MARCH TERM 2022
NO. 2617**

**PLAINTIFF ALICE STILLs'S MOTION FOR ADMISSION
PRO HAC VICE OF BENJAMIN WHITING**

Plaintiff Alice Stills, on her own behalf and as Parent and Natural Guardian of M.E., a Minor, through the undersigned sponsoring counsel, moves this Court to admit Benjamin Whiting *pro hac vice* as co-counsel on behalf of Plaintiff for all purposes allowed by law in the above captioned matter. In support of this motion, Ms. Stills states as follows:

1. This is a civil action about the development of necrotizing enterocolitis ("NEC"), and related injuries, by a premature infant due to the use of the Defendant Manufacturers' cow's

milk-based preterm infant feeding products at the Defendant Hospital. Plaintiff Alice Stills, on her own behalf and as Parent and Natural Guardian of M.E., a Minor, is represented in this action by the undersigned counsel who is admitted to the Bar of this Commonwealth to practice law.

2. The general rule for admission *pro hac vice* in the Commonwealth is stated in Pa. B.A.R. 301(a):

An attorney, barrister or advocate who is qualified to practice in the courts of another state or of a foreign jurisdiction may be specially admitted to the bar of this Commonwealth for purposes limited to a particular case. An attorney, barrister or advocate admitted *pro hac vice* in a case shall not thereby be authorized to act as attorney of record in the case.

3. Mr. Whiting satisfies the requirements of Pa. B.A.R. 301(a). As set forth in the candidate verification pursuant to Pa. R.C.P. 1012.1(c), attached as **Exhibit A**, and incorporated herein, Mr. Whiting is an attorney with the law firm Keller Postman LLC, located at 150 N Riverside Plaza, Suite 4100, Chicago, Illinois 60606. Mr. Whiting was admitted to the practice of law in the State of Illinois and in the State of New York in 2011. Mr. Whiting has been and remains a member in good standing with the Bar.

4. Mr. Whiting has not been the subject of disciplinary action in any court or before any Bar.

5. Ms. Stills has retained the services of Mr. Whiting and his firm in regard to the above captioned lawsuit. This matter is a complex product liability lawsuit and Mr. Whiting has extensive and specialized knowledge of this type of case.

6. Mr. Whiting seeks admission *pro hac vice* under Rule 301 of the Pennsylvania Bar Admission Rules for the purpose of participating with the undersigned counsel in further proceedings and trial in the above captioned matter.

7. All fees required by 204 Pa. Code § 81.505 have been paid and the Pennsylvania IOLTA Board's acknowledgement letter is attached as **Exhibit B**. Mr. Whiting's law firm will pay any city business and wage taxes required.

8. Mr. Whiting's good reputation and competence is attested to in the sponsor verification attached pursuant to Pa. R.C.P. 1012.1(d)(2) as **Exhibit C**, and incorporated herein.

9. As set forth in the motion and the exhibits incorporated herein, there exists no good cause for denial of Ms. Stills's Motion for Admission *Pro Hac Vice* of Benjamin Whiting. No party will be prejudiced by Mr. Whiting's admission *pro hac vice*.

WHEREFORE, Plaintiff Alica Stills, on her own behalf and as Parent and Natural Guardian of M.E., a Minor, respectfully requests that this Court enter the attached Order granting admission *pro hac vice* in this matter for Benjamin Whiting, Esquire.

Respectfully submitted,

KLINE & SPECTER, P.C.

By: /s/ Tobias L. Millrood
Tobias L. Millrood, Esq.
Attorney for Plaintiff Alice Stills, on her
own behalf and as Parent and Natural
Guardian of M.E., a Minor

Dated: July 14, 2023

CERTIFICATE OF SERVICE

I, Tobias L. Millrood, hereby certify that a true and correct copy of the foregoing Motion for Admission *Pro Hac Vice* of Benjamin Whiting was filed this date via the First Judicial District of Pennsylvania's Electronic Filing System, which thereby deems the foregoing as served on all counsel of record pursuant to Rule 205.4(g)(2)(ii) of the Pennsylvania Rules of Civil Procedure.

/s/ Tobias L. Millrood
TOBIAS L. MILLROOD, ESQUIRE

Dated: July 14, 2023

FILED
14 JUL 2023 04:59 pm
Civil Administration
P. CHROY

EXHIBIT A

KLINE AND SPECTER, P.C.

By: TOBIAS L. MILLROOD, ESQUIRE
ELIZABETH A. CRAWFORD, ESQUIRE
JOHN P. O'NEILL, ESQUIRE

Attorney I.D. No. 77764 / 313702 / 205677

1525 Locust Street

Philadelphia, PA 19102

(215) 772-1000 phone

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Elizabeth.Crawford@Klinespecter.com

Jack.Oneill@klinespecter.com

ALICE STILLS, on her own behalf and as Parent
and Natural Guardian of M.E., a Minor,

Plaintiff,

v.

MEAD JOHNSON & COMPANY, LLC, MEAD
JOHNSON NUTRITION COMPANY, ABBOTT
LABORATORIES, THE PENNSYLVANIA HOSPITAL
OF THE UNIVERSITY OF PENNSYLVANIA HEALTH
SYSTEM d/b/a PENNSYLVANIA HOSPITAL, and
THE TRUSTEES OF THE UNIVERSITY OF
PENNSYLVANIA d/b/a PENN MEDICINE,

Defendants.

**IN THE COURT OF COMMON PLEAS
PHILADELPHIA COUNTY**

CIVIL TRIAL DIVISION

**MARCH TERM 2022
NO. 2617**

CANDIDATE VERIFICATION STATEMENT PURSUANT TO PA. R.C.P. 1012.1(c)

I, Benjamin Whiting, Esquire, being duly sworn, state as follows:

1. I am an attorney and have been duly qualified and admitted to practice before the highest court of the State of New York since April 14, 2011, New York license number 4935888, and before the highest court of the State of Illinois since November 10, 2011, Illinois license number 630721.

2. I am also admitted to the United States District Court for the Central District of Illinois, Northern District of Illinois, Southern District of Illinois, and the Southern District of New York and the United States Circuit Court of Appeals for the Federal Circuit.

3. I am affiliated with the law firm Keller Postman LLC, 150 N Riverside Plaza, Suite 4100, Chicago, Illinois 60606.

4. I have never been suspended, disbarred, or otherwise disciplined.

5. I am not currently subject to any disciplinary proceedings.

6. I have applied for admission *pro hac vice* in the following cases in the Philadelphia Court of Common Pleas:

- a. *Abdullah v. Mead Johnson & Company, LLC et al.*, March Term, 2022, No. 2583
- b. *McMillian v. Mead Johnson & Company, LLC et al.*, April Term, 2022, No. 0140
- c. *Carter v. Mead Johnson & Company, LLC et al.*, March Term, 2022, No. 2588
- d. *Drayton v. Mead Johnson & Company, LLC et al.*, March Term, 2022, No. 2594
- e. *Stills v. Mead Johnson & Company, LLC et al.*, March Term, 2022, No. 2617
- f. *Mays v. Mead Johnson & Company, LLC et al.*, March Term, 2022, No. 2963
- g. *Padilla v. Mead Johnson & Company, LLC et al.*, March Term, 2022, No. 2969
- h. *Kajuffa v. Mead Johnson & Company, LLC et al.*, March Term, 2022, No. 2978
- i. *Ross v. Mead Johnson & Company, LLC et al.*, March Term, 2022, No. 2981
- j. *Parker v. Mead Johnson & Company, LLC et al.*, March Term, 2022, No. 2983
- k. *Henderson v. Mead Johnson & Company, LLC et al.*, April Term, 2022, No. 0127
- l. *Williams v. Mead Johnson & Company, LLC et al.*, April Term, 2022, No. 0141
- m. *Sanders v. Mead Johnson & Company, LLC et al.*, April Term, 2022, No. 0153
- n. *Walker-Savage v. Mead Johnson & Company, LLC et al.*, April Term, 2022, No. 0156
- o. *Thomas v. Mead Johnson & Company, LLC et al.*, April Term, 2022, No. 0158
- p. *Wieger v. Mead Johnson & Company, LLC et al.*, April Term, 2022, No. 2601
- q. *Gray v. Mead Johnson & Company, LLC et al.*, April Term, 2022, No. 0216

7. No motions for admission *pro hac vice* have been denied.

8. I shall comply with and be bound by the applicable statutes, case law and procedural rules of the Commonwealth of Pennsylvania, including the Pennsylvania Rules of Professional Conduct.

9. I shall submit to the jurisdiction of the Pennsylvania courts and the Pennsylvania Disciplinary Board with respect to acts and omissions occurring during the appearance in the matter for which admission *pro hac vice* is being sought.

10. I have consented to the appointment of Tobias L. Millrood, Esquire as the agent upon whom service of process shall be made for all actions, including disciplinary actions, that may arise out of the practice of law in the matter for which admission *pro hac vice* is sought.

11. The undersigned verifies that the facts set forth in the foregoing candidate verification are true and correct to the best of his knowledge, information, and belief and understands that any false statements are made subject to the penalties of 18 Pa. Code § 4904 relating to unsworn falsification to authorities.

/s/ Benjamin Whiting
BENJAMIN WHITING, ESQUIRE

Dated: July 14, 2023

VERIFICATION

I, Benjamin J. Whiting, Esquire hereby verify that the facts contained in the *Pro Hac Vice* motions specified below are true and correct to the best of my knowledge, information and belief. I further understand that these statements are made subject to penalties of 18 Pa. C.S.A. 4904 relating to unsworn falsification to authorities.

- a. *Carter v. Mead Johnson & Company, LLC et al.*, March Term, 2022, No. 2588
- b. *Drayton v. Mead Johnson & Company, LLC et al.*, March Term, 2022, No. 2594
- c. *Stills v. Mead Johnson & Company, LLC et al.*, March Term, 2022, No. 2617
- d. *Mays v. Mead Johnson & Company, LLC et al.*, March Term, 2022, No. 2963
- e. *Padilla v. Mead Johnson & Company, LLC et al.*, March Term, 2022, No. 2969
- f. *Kajuffa v. Mead Johnson & Company, LLC et al.*, March Term, 2022, No. 2978
- g. *Ross v. Mead Johnson & Company, LLC et al.*, March Term, 2022, No. 2981
- h. *Parker v. Mead Johnson & Company, LLC et al.*, March Term, 2022, No. 2983
- i. *Henderson v. Mead Johnson & Company, LLC et al.*, April Term, 2022, No. 0127
- j. *Williams v. Mead Johnson & Company, LLC et al.*, April Term, 2022, No. 0141
- k. *Sanders v. Mead Johnson & Company, LLC et al.*, April Term, 2022, No. 0153
- l. *Walker-Savage v. Mead Johnson & Company, LLC et al.*, April Term, 2022, No. 0156
- m. *Thomas v. Mead Johnson & Company, LLC et al.*, April Term, 2022, No. 0158
- n. *Wieger v. Mead Johnson & Company, LLC et al.*, April Term, 2022, No. 2601
- o. *Gray v. Mead Johnson & Company, LLC et al.*, April Term, 2022, No. 0216



Benjamin J. Whiting, Esquire

DATE: 7/12/2023

FILED
14 JUL 2023 04:59 pm
Civil Administration
P. CHROY

EXHIBIT B



SUPREME COURT OF PENNSYLVANIA
PENNSYLVANIA INTEREST ON
LAWYERS TRUST ACCOUNT BOARD

May 26, 2023

BENJAMIN WHITING, Esq.
KELLER POSTMAN
150 N. RIVERSIDE PLAZA
SUITE 4100
CHICAGO, IL 60606

SENT TO BENJAMIN WHITING VIA Email: BEN.WHITING@KELLERPOSTMAN.COM

Dear Attorney WHITING:

This letter serves as the fee payment certification referenced in 204 Pa Code §81.503 and acknowledges receipt of the \$375.00 fee paid by Online Payment on this date related to your pursuit for admission *pro hac vice* in the case identified as Stills v. Mead Johnson & Company, LLC et al., no. 2617, filed in Court of Common Pleas of Philadelphia County.

You should refer to Pa Rule of Civil Procedure 1012.1, local court rules, and other regulations of 204 Pa Code §81.501 et. seq. concerning additional requirements related to seeking *pro hac vice* admission.

Sincerely,

A handwritten signature in blue ink that reads "Stephanie S. Libhart".

Stephanie S. Libhart
Executive Director

cc: TOBIAS LAEL MILLROOD, Esq.
tobi.millrood@klinespecter.com

Pennsylvania Judicial Center
601 Commonwealth Ave., Ste. 2400
PO Box 62445, Harrisburg, PA 17106-2445
717/238-2001 · 888/PA-IOLTA (724-6582) · 717/238-2003 FAX
paiolta@pacourts.us · www.paiolta.org

FILED
14 JUL 2023 04:59 pm
Civil Administration
P. CHROY

EXHIBIT C

KLINE AND SPECTER, P.C.

By: TOBIAS L. MILLROOD, ESQUIRE
ELIZABETH A. CRAWFORD, ESQUIRE
JOHN P. O'NEILL, ESQUIRE

Attorney I.D. No. 77764 / 313702 / 205677

1525 Locust Street

Philadelphia, PA 19102

(215) 772-1000 phone

(215) 792-5519 fax

Tobi.Millrood@klinespecter.com

Elizabeth.Crawford@Klinespecter.com

Jack.Oneill@klinespecter.com

ALICE STILLS, on her own behalf and as Parent
and Natural Guardian of M.E., a Minor,

Plaintiff,

v.

MEAD JOHNSON & COMPANY, LLC, MEAD
JOHNSON NUTRITION COMPANY, ABBOTT
LABORATORIES, THE PENNSYLVANIA HOSPITAL
OF THE UNIVERSITY OF PENNSYLVANIA HEALTH
SYSTEM d/b/a PENNSYLVANIA HOSPITAL, and
THE TRUSTEES OF THE UNIVERSITY OF
PENNSYLVANIA d/b/a PENN MEDICINE,

Defendants.

**IN THE COURT OF COMMON PLEAS
PHILADELPHIA COUNTY**

CIVIL TRIAL DIVISION

**MARCH TERM 2022
NO. 2617**

SPONSOR VERIFICATION STATEMENT PURSUANT TO PA. R.C.P. 1012.1(d)

I, Tobias L. Millrood, being duly sworn, state as follows:

1. I am an attorney duly admitted to practice law before this Court and am a partner in the law firm Kline & Specter, P.C., counsel for Plaintiff Alice Stills, on her own behalf and as Parent and Natural Guardian of M.E., a Minor, in the above captioned matter.

2. I submit this verification in support of Ms. Stills's Motion for Admission *Pro Hac Vice* of Benjamin Whiting for purposes of serving as co-counsel to Ms. Stills.

3. After reasonable investigation, I believe Benjamin Whiting, Esquire, is a reputable and competent attorney and I am in a position to recommend his admission.

4. I have previously acted as the sponsor of other candidates for admission *pro hac vice* in this and other courts of record in this Commonwealth.

5. The proceeds from the settlement of a cause of action in which Benjamin Whiting, Esquire, is granted admission *pro hac vice* shall be received, held, distributed, and accounted for in accordance with Rule 1.15 of the Pennsylvania Rules of Professional Conduct, including the IOLTA provisions thereof, if applicable.

6. The undersigned verifies that the facts set forth in the foregoing sponsor verification are true and correct to the best of her knowledge, information, and belief and understands that any false statements are made subject to the penalties of 18 Pa. Code § 4904 relating to unsworn falsification to authorities.

/s/ Tobias L. Millrood
TOBIAS L. MILLROOD, ESQUIRE

Dated: July 14, 2023

Civil Administration

Case ID: 220302617
Control No.: 23072525

EXHIBIT A-35

**IN THE FIRST JUDICIAL DISTRICT OF PENNSYLVANIA
COURT OF COMMON PLEAS OF PHILADELPHIA
CIVIL TRIAL DIVISION**

ABDULLAH ETAL	:	CASE ID: 220302583
	:	
VS	:	
	:	
MEAD JOHNSON & COMPANY	:	

ORDER

AND NOW, this 24th day of July 2023, it is hereby ORDERED that Plaintiff may file an amended complaint on or before September 8, 2023 (or other date agreed to by counsel). It is

FURTHER ORDERED, this order shall also apply to the following captioned matters:

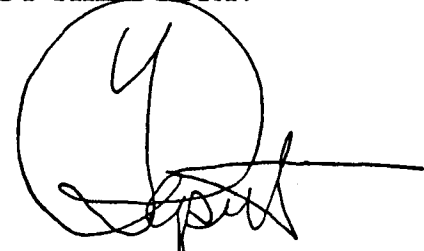
220302588	CARTER ETAL VS MEAD JOHNSON & COMPANY
220302594	DRAYTON ETAL VS MEAD JOHNSON & COMPANY
220302601	WIEGER ETAL VS MEAD JOHNSON & COMPANY
220302606	TAYLOR ETAL VS MEAD JOHNSON & COMPANY
220302614	WIEGER ETAL VS MEAD JOHNSON & COMPANY
220302617	STILLS ETAL VS MEAD JOHNSON NUTRITION
220302963	MAYS ETAL VS MEAD JOHNSON & COMPANY
220302967	WATSON ETAL VS MEAD JOHNSON & COMPANY
220302969	PADILLA ETAL VS MEAD JOHNSON & COMPANY
220302978	KAJUFFA ETAL VS MEAD JOHNSON & COMPANY
220302981	ROSS ETAL VS MEAD JOHNSON & COMPANY
220302983	PARKER ETAL VS MEAD JOHNSON & COMPANY
220302986	WIGGINS ETAL VS MEAD JOHNSON & COMPANY
220400127	HENDERSON ETAL VS MEAD JOHNSON & COMPANY
220400136	HINES ETAL VS MEAD JOHNSON & COMPANY
220400138	WITHERSPOON ETAL VS MEAD JOHNSON & COMPANY
220400140	MCMILLIAN ETAL VS MEAD JOHNSON & COMPANY
220400141	WILLIAMS ETAL VS MEAD JOHNSON & COMPANY
220400142	MOMENT ETAL VS MEAD JOHNSON & COMPANY
220400145	WHITFIELD ETAL VS MEAD JOHNSON & COMPANY
220400153	SANDERS ETAL VS MEAD JOHNSON & COMPANY
220400156	WALKER-SAVAGE ETAL VS MEAD JOHNSON & COMPANY
220400158	THOMAS ETAL VS MEAD JOHNSON & COMPANY
220400159	SHORT ETAL VS MEAD JOHNSON & COMPANY
220400162	JOHNSON ETAL VS MEAD JOHNSON & COMPANY
220400208	GOODMOND ETAL VS MEAD JOHNSON & COMPANY
220400212	GOODMOND ETAL VS MEAD JOHNSON & COMPANY
220400216	GRAY ETAL VS MEAD JOHNSON & COMPANY

ORDER-Still's Etal Vs Mead Johnson Nutrition Company Etal



22030261700051

BY THE COURT:

A handwritten signature in black ink, featuring a large, stylized capital 'J' that loops around and under the rest of the signature. The signature is written over a horizontal line.

CARPENTER, J.

EXHIBIT A-36

**IN THE FIRST JUDICIAL DISTRICT OF PENNSYLVANIA
COURT OF COMMON PLEAS OF PHILADELPHIA
CIVIL TRIAL DIVISION**

ABDULLAH ETAL	:	CASE ID: 220302583
	:	
VS	:	
	:	
MEAD JOHNSON & COMPANY	:	

ORDER

AND NOW, this 24th day of July 2023, it is hereby **ORDERED** that all discovery is to be completed by June 3, 2024 and all other case management deadlines to extend therefrom. It is **FURTHER ORDERED**, this extension shall also apply to the following captioned matters:

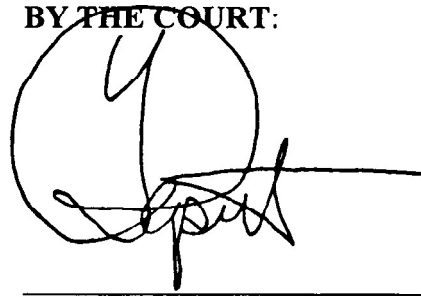
220302588	CARTER ETAL VS MEAD JOHNSON & COMPANY
220302594	DRAYTON ETAL VS MEAD JOHNSON & COMPANY
220302601	WIEGER ETAL VS MEAD JOHNSON & COMPANY
220302606	TAYLOR ETAL VS MEAD JOHNSON & COMPANY
220302614	WIEGER ETAL VS MEAD JOHNSON & COMPANY
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220400208	GOODMOND ETAL VS MEAD JOHNSON & COMPANY
220400212	GOODMOND ETAL VS MEAD JOHNSON & COMPANY
220400216	GRAY ETAL VS MEAD JOHNSON & COMPANY

ORDER-Still's Etal Vs Mead Johnson Nutrition Company Etal



22030261700052

BY THE COURT:

A handwritten signature in black ink, appearing to be 'J. Carpenter', written over a horizontal line.

CARPENTER, J.

EXHIBIT A-37



IN THE COURT OF COMMON PLEAS OF PHILADELPHIA COUNTY
FIRST JUDICIAL DISTRICT OF PENNSYLVANIA
TRIAL DIVISION – CIVIL

STILLS ETAL

VS

MEAD JOHNSON NUTRITION
COMPANY ETAL

March Term 2022

No. 02617

REVISED CASE MANAGEMENT ORDER

Be advised that the Case Management Order issued for the above-captioned action has been revised as follows:

1. All discovery shall be completed not later than 03-JUN-2024.
2. Plaintiff shall submit expert reports not later than 01-JUL-2024.
3. Defendant shall submit expert reports not later than 05-AUG-2024.
4. All pre-trial motions other than motions in limine shall be filed not later than 05-AUG-2024.
5. A settlement conference will be scheduled any time after 03-SEP-2024.
6. A pre-trial conference will be scheduled at any time after 04-NOV-2024.
7. It is expected that this case shall be ready for trial by 02-DEC-2024.

All other terms and conditions on the original Case Management Order will remain in full force and effect.

BY THE COURT:

LINDA CARPENTER, J.
TEAM LEADER

24-JUL-2023

FJB89004(REV. 5/21/18)

RVCMO-Stills Etal Vs Mead Joh



22030261700056

EXHIBIT A-38

FILED
 14 JUL 2023 04:59 pm
Civil Administration
 P. CHROY

ALICE STILLS, on her own behalf and as Parent
 and Natural Guardian of M.E., a Minor,

Plaintiff,

v.

MEAD JOHNSON & COMPANY, LLC, MEAD
 JOHNSON NUTRITION COMPANY, ABBOTT
 LABORATORIES, THE PENNSYLVANIA HOSPITAL
 OF THE UNIVERSITY OF PENNSYLVANIA HEALTH
 SYSTEM d/b/a PENNSYLVANIA HOSPITAL, and
 THE TRUSTEES OF THE UNIVERSITY OF
 PENNSYLVANIA d/b/a PENN MEDICINE,

Defendants.

IN THE COURT OF COMMON PLEAS
 PHILADELPHIA COUNTY

CIVIL TRIAL DIVISION

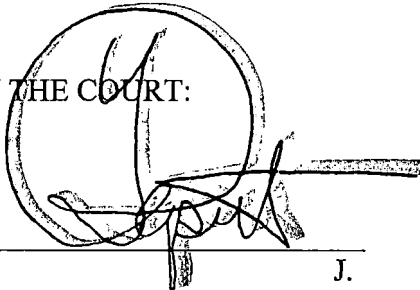
MARCH TERM 2022
 NO. 2617

ORDER

AND NOW THIS 14th day of AUGUST, 2023, upon consideration of Plaintiff

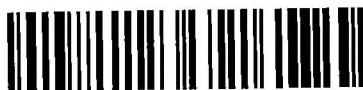
Alice Stills's Motion for Admission *Pro Hac Vice* of Benjamin Whiting, it is hereby **ORDERED** that the motion is **GRANTED**. It is further **ORDERED** that pursuant to Pennsylvania Rule of Civil Procedure 1012.1, Pennsylvania Bar Admission Rule 301, and 204 Pa. Code § 81.503, Benjamin Whiting, Esquire, is hereby specially admitted to the Bar of this Commonwealth for purposes limited to this particular civil action to represent Plaintiff Alice Stills, on her own behalf and as Parent and Natural Guardian of M.E., a Minor. Counsel *pro hac vice* shall pay all city business and wage taxes as required by the Court.

BY THE COURT:



J.

220302617-Stills Etal Ve Mead Johnson Nutrition Company Etal



22030261700064

Case ID: 220302617
 Control No.: 23072525

EXHIBIT A-39

WELSH AND RECKER, P.C.
Catherine M. Recker (PA Bar No. 56813)
Amy B. Carver (PA Bar No. 84819)
Richard D. Walk , III (PA Bar No. 329420)
306 Walnut Street
Philadelphia, PA 19106
215-972-6430

ATTORNEYS FOR DEFENDANT MEAD
JOHNSON & COMPANY, LLC AND MEAD
JOHNSON NUTRITION COMPANY



Alice Stills, on her own behalf and as Parent
and Natural Guardian of M.E., a Minor,
Plaintiff,

v.

Mead Johnson & Company, LLC, et al.,
Defendants.

PHILADELPHIA COUNTY COURT OF
COMMON PLEAS

March Term, 2022

No. 220302617

NOTICE OF APPEARANCE

TO THE PROTHONOTARY:

Kindly enter the appearance of Catherine M. Recker, Amy B. Carver, and Richard D. Walk, III as attorneys for Mead Johnson & Company, LLC and Mead Johnson Nutrition Company in the above-captioned matter.

Dated: August 16, 2023

Respectfully submitted,

/s/ Richard D. Walk, III

Catherine M. Recker (PA Bar No. 56813)
Amy B. Carver (PA Bar No. 84819)
Richard D. Walk , III (PA Bar No. 329420)
WELSH & RECKER, P.C.
306 Walnut St.
Philadelphia, PA 19106
Tel: (215) 972-6430
Fax: 1-985-617-1021
cmrecker@welshrecker.com
abcarver@welshrecker.com
rwalk@welshrecker.com

CERTIFICATE OF SERVICE

I, Richard D. Walk, III, hereby certify that I caused a true and correct copy of the foregoing Notice of Appearance to be filed with the Prothonotary of the Court of Common Pleas of Philadelphia County using the ECF system, and the filing is available for viewing and download from the ECF system, and a true and correct copy was served via ECF on all counsel of record registered with the ECF system.

Dated: August 16, 2023

/s/ Richard D. Walk, III

EXHIBIT A-40

KLINE & SPECTER, P.C.

By:

Thomas R. Kline, Esq.
Tobias L. Millrood, Esq.
Elizabeth A. Crawford, Esq.
Timothy A. Burke, Esq.
John P. O'Neill, Esq.

Attorney I.D. Nos.: 28895 / 77764 / 313702 /
320927 / 205677

125 Locust Street, 19th Floor

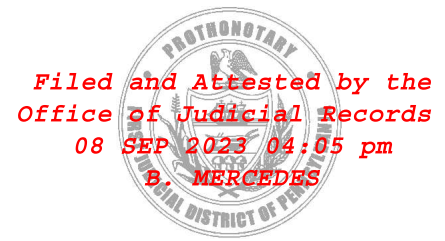
Philadelphia, PA 19102

Telephone: (215) 772-1000

Tobi.millrood@klinespecter.com

Elizabeth.crawford@klinespecter.com

Jack.oneill@klinespecter.com



ALICE STILLS, on her own behalf and as Parent
and Natural Guardian of M.E., a Minor,

Plaintiff,

v.

MEAD JOHNSON & COMPANY, LLC, MEAD
JOHNSON NUTRITION COMPANY, ABBOTT
LABORATORIES, THE TRUSTEES OF THE
UNIVERSITY OF PENNSYLVANIA d/b/a PENN
MEDICINE, and PENNSYLVANIA HOSPITAL OF THE
UNIVERSITY OF PENNSYLVANIA HEALTH SYSTEM
d/b/a PENNSYLVANIA HOSPITAL,

Defendants.

: **IN THE COURT OF COMMON PLEAS**
: **PHILADELPHIA COUNTY**
:
: **CIVIL TRIAL DIVISION**
:
: **MARCH TERM 2022**
: **NO. 2617**

NOTICE TO PLEAD AND DEFEND

NOTICE

You have been sued in court. If you wish to defend against the claims set forth in the following pages, you must take action within twenty (20) days after this complaint and notice are served, by entering a written appearance personally or by attorney and filing in writing with the court your defenses or objections to the claims set forth against you. You are warned that if you fail to do so the case may proceed without you and a judgment may be entered against you by the court without further notice for any money claimed in the complaint or for any other claim or relief requested by the plaintiff. You may lose money or property or other rights important to you.

YOU SHOULD TAKE THIS PAPER TO YOUR LAWYER

ADVISO

Le han demandado a usted en la corte. Si usted quiere defenderse de estas demandas expuestas en las paginas siguientes, usted tiene veinte (20) dias de plazo al partir de la fecha de la demanda y la notificacion. Hace falta asentar una comparencia escrita o en persona o con un abogado y entregar a la corte en forma escrita sus defensas o sus objeciones a las demandas en contra de su persona. Sea avisado que si usted no se defiende, la corte tomara medidas y puede continuar la demanda en contra suya sin previo aviso o notificacion. Ademas, la corte pueda decidir a favor del demandante y requiere que usted cumpla con todas las provisiones de esta demanda. Usted puede perder dinero o sus propiedades u otros derechos importantes para usted.

LLEVE ESTA DEMANDA A UN ABOGADO INMEDIATAMENTE, SI

AT ONCE. IF YOU DO NOT HAVE A LAWYER, GO TO
OR TELEPHONE THE OFFICE SET FORTH BELOW TO
FIND OUT WHERE YOU CAN GET LEGAL HELP.

Lawyer Referral Service
Philadelphia Bar Association
1101 Market Street, 11th Floor
Philadelphia, PA 19107
(215) 238-6338

NO TIENE ABOGADO O SI NO TIENE EL DINERO SUFICIENTE DE
PAGAR TAL SERVICIO, VAYA EN PERSONA O LLAME POR
TELEFONO A LA OFICINA CUYA DIRECCION SE ENCUENTRA
ESCRITA ABAJO PARA AVERIGUAR DONDE SE PUEDE
CONSEGUIR ASISTENCIA LEGAL.

Lawyer Referral Service
Philadelphia Bar Association
1101 Market Street, 11th Floor
Philadelphia, PA 19107
(215) 238-6338

KLINE & SPECTER, P.C.

By:

Thomas R. Kline, Esq.

Tobias L. Millrood, Esq.

Elizabeth A. Crawford, Esq.

Timothy A. Burke, Esq.

John P. O'Neill, Esq.

Attorney I.D. Nos.: 28895 / 77764 / 313702 /
320927 / 205677

125 Locust Street, 19th Floor

Philadelphia, PA 19102

Telephone: (215) 772-1000

Tobi.millrood@klinespecter.com

Elizabeth.crawford@klinespecter.com

Jack.oneill@klinespecter.com

ALICE STILLS, on her own behalf and as Parent
and Natural Guardian of M.E., a Minor,

Plaintiff,

V.

MEAD JOHNSON & COMPANY, LLC, MEAD
JOHNSON NUTRITION COMPANY, ABBOTT
LABORATORIES, THE TRUSTEES OF THE
UNIVERSITY OF PENNSYLVANIA d/b/a PENN
MEDICINE, and PENNSYLVANIA HOSPITAL OF THE
UNIVERSITY OF PENNSYLVANIA HEALTH SYSTEM
d/b/a PENNSYLVANIA HOSPITAL,

Defendants.

: **IN THE COURT OF COMMON PLEAS**
 : **PHILADELPHIA COUNTY**
 :
 : **CIVIL TRIAL DIVISION**
 :
 : **MARCH TERM 2022**
 : **NO. 2617**

FIRST AMENDED COMPLAINT

Plaintiff brings this Amended Complaint and Demand for Jury Trial (the “Amended Complaint”) against Mead Johnson & Company, LLC, Mead Johnson Nutrition Company, and Abbott Laboratories (collectively “the Defendant Manufacturers”), and The Trustees of the University of Pennsylvania d/b/a Penn Medicine and Pennsylvania Hospital of the University of

Pennsylvania Health System d/b/a Pennsylvania Hospital (collectively “Penn Medicine” or “Pennsylvania Hospital”), together “Defendants.” Plaintiff alleges the following upon personal knowledge as to Plaintiff’s own acts and experiences and upon information and belief, including investigation conducted by Plaintiff’s attorneys, as to all other matters.

I. INTRODUCTION

1. This action arises out of the injuries suffered by a premature infant (the “Injured Infant”) who was given the Defendant Manufacturers’ cow’s milk-based infant feeding products at Pennsylvania Hospital. Pennsylvania Hospital, managed by Penn Medicine, acquired and supplied the Defendant Manufacturers’ products to the Injured Infant and negligently failed to warn of their unreasonably dangerous properties in a reasonable manner. This caused the Injured Infant to develop necrotizing enterocolitis (“NEC”), a life-altering and potentially deadly disease that largely affects premature babies who are given cow’s milk-based feeding products. As a result, the Injured Infant was seriously injured, resulting in long term health effects and accompanying harm to their parent (“the Plaintiff Parent”).

2. Plaintiff brings these causes of action against Defendants to recover for injuries that are the direct and proximate result of the Injured Infant’s consumption of the Defendant Manufacturers’ unreasonably dangerous cow’s milk-based infant feeding products, which were acquired and supplied without adequate warning to the Injured Infant at Pennsylvania Hospital, owned and operated by Penn Medicine.

II. PARTIES

3. Plaintiff Alice Stills is a natural adult person and a resident of Pennsylvania. Ms. Stills is the parent and natural guardian of M.E., a minor. Ms. Stills’s address is 656 N Conestoga Street, Philadelphia, Pennsylvania 19131.

4. Defendant Mead Johnson Nutrition Company is a corporation, incorporated under the laws of the State of Delaware. Its principal place of business is Illinois. Defendant Mead Johnson & Company, LLC, is a limited liability company, organized under the laws of the State of Delaware. Its citizenship is that of its sole member, Mead Johnson Nutrition Company. Defendants Mead Johnson Nutrition Company and Mead Johnson & Company, LLC, (together, “Mead”) are manufacturers of cow’s milk-based infant feeding products and market many of these products under the “Enfamil” brand name.

5. Defendant Abbott Laboratories (“Abbott”) is a corporation, incorporated under the laws of the State of Illinois. Its principal place of business is in Illinois. Abbott is a manufacturer of cow’s milk-based infant feeding products and markets many of its products under the “Similac” brand name.

6. Defendant The Pennsylvania Hospital of the University of Pennsylvania Health System d/b/a Pennsylvania Hospital is a non-profit corporation incorporated and registered to do business under the laws of the Commonwealth of Pennsylvania. Its principal place of business is Philadelphia, Pennsylvania. Pennsylvania Hospital is a registered name of The Pennsylvania Hospital of the University of Pennsylvania Health System. The sole member of The Pennsylvania Hospital of the University of Pennsylvania Health System is The Trustees of the University of Pennsylvania.

7. Defendant The Trustees of the University of Pennsylvania d/b/a Penn Medicine is a non-profit corporation registered to do business in the Commonwealth of Pennsylvania. Its principal place of business is Philadelphia, Pennsylvania. Penn Medicine is a registered name of The Trustees of the University of Pennsylvania.

III. JURISDICTION AND VENUE

8. This Court has jurisdiction in this matter pursuant to 42 Pa. C.S.A. § 931. Defendants conduct authorized business in the Commonwealth of Pennsylvania. They have sufficient minimum contacts with and purposefully avail themselves of the markets of this Commonwealth. This suit arises out of Defendants' forum-related activities, such that the Court of Common Pleas of Philadelphia County's exercise of jurisdiction would be consistent with traditional notions of fair play and substantial justice.

9. Venue is proper in the Court of Common Pleas of Philadelphia County pursuant to Rules 1006(b), 1006(c)(1), and 2179(a) of the Pennsylvania Rules of Civil Procedure because Defendants are corporations or similar entities that regularly conduct business in Philadelphia County, which is also the county where Plaintiff's causes of action arose, and the county where the occurrences took place out of which Plaintiff's causes of action arose.

10. This action is not subject to the Compulsory Arbitration Program of the Court of Common Pleas of Philadelphia County because the amount in controversy, excluding interest and costs, is in excess of \$50,000.

IV. FACTUAL ALLEGATIONS

M.E.'s NEC Diagnosis

11. M.E. was born prematurely at Pennsylvania Hospital in Philadelphia, Pennsylvania on September 28, 2007.

12. At birth, M.E.'s gestational age was approximately 28 weeks and he weighed 907 grams. Upon information and belief, M.E. was fed Similac and/or Enfamil cow's milk-based products by staff at Pennsylvania Hospital after his birth.

13. Upon information and belief, M.E. developed NEC after ingesting Defendant Manufacturers' products.

14. M.E.'s diagnosis of NEC occurred during his course of treatment at Defendant Hospital's NICU. M.E. suffered injuries, including but not limited to, a diagnosis of NEC, treatment with antibiotics and surgery, feeding difficulties, neurological injuries, developmental delays, and growth issues and he continues to suffer other long-term health effects.

***Cow's Milk-Based Feeding Products Are Known to Cause
NEC***

15. NEC is a devastating disease that is the most frequent and lethal gastrointestinal disorder affecting preterm infants. NEC develops when harmful bacteria breach the walls of the intestine, causing portions of the intestine to become inflamed and often to die. Once NEC develops, the condition can progress rapidly from mild feeding intolerance to systemic and fatal sepsis. Up to 30 percent of NEC-diagnosed infants die from the disease.

16. Preterm and low-birth-weight infants are especially susceptible to NEC because of their underdeveloped digestive systems. Extensive scientific research, including numerous randomized controlled trials, has confirmed that cow's milk-based feeding products cause NEC in preterm and low-birth-weight infants, which in turn may lead to other medical complications, surgeries, long-term health problems, and death.

Safer, Nutritionally Superior Alternatives to Cow's Milk-Based Products Exist

17. A range of options are available that allow preterm and low-birth-weight infants to be fed exclusively human milk-based nutrition. For example, in addition to the mother's own milk, an established network delivers pasteurized donor breast milk to hospitals nationwide. Moreover, hospitals have access to shelf-stable formula and fortifiers derived from pasteurized breast milk.

18. A diet based exclusively on breast milk and breast milk fortifiers provides all the nutrition necessary to support premature and low-birth-weight infants without the elevated risk of NEC associated with cow's milk-based products.

19. The Defendant Manufacturers' products not only pose a threat to infants' health, but also displace the breast milk they could otherwise receive. This displacement only increases infants' vulnerability to NEC.

20. Breast milk-based nutrition nourishes infants while creating a significantly lower risk of NEC.

21. At the time the Injured Infant was fed the Defendant Manufacturers' products, the science clearly demonstrated to Defendants that these products cause NEC and greatly increase the likelihood that a baby will develop NEC, leading to severe injury and often death.

22. Despite the scientific consensus that the Defendant Manufacturers' cow's milk-based products present a dire threat to the health and development of preterm infants, the Defendant Manufacturers have made no changes to their products or the products' packaging, guidelines, instructions, or warnings. Instead, they have continued to sell their unreasonably dangerous products. In addition, they incentivize hospitals that know the risks to use their products by providing them to the hospital for free or at a significant discount, in order that vulnerable infants and their families will become accustomed to using their products before discharge. And, in fact, the Defendant Manufacturers offer contracts to hospitals—which the hospitals accept—that actually *prevent* the health care providers from offering alternative products—even safer ones—on pain of risking the hospital's advantageous formula pricing strategy.

Ms. Stills Discovers Her Claim

23. Because of the Defendants' concealment and misrepresentations, described more fully herein, Ms. Stills did not know, and had no reason to know or suspect, that M.E.'s NEC could have been caused by the Defendant Manufacturers' products.

***Despite Exercising Diligence, a Reasonable Investigation Did Not Reveal and
Would Not Have Revealed a Factual Basis Earlier
Because Defendants Hid the Cause of NEC from Ms. Stills***

24. Despite exercising reasonable diligence, Ms. Stills was unable to have made the discovery earlier via a reasonable investigation because the Defendants in this litigation concealed the wrongful cause of M.E.'s injuries.

25. Not one person at Penn Medicine mentioned that the Defendant Manufacturers' formula products could have caused M.E.'s injuries. Penn Medicine's response at the time did not give Ms. Stills any reason to suspect any wrongdoing on the part of the Defendants.

26. Ms. Stills is a layperson with no medical background or training that would have given her any reason to doubt the response she received from her Penn Medicine health care providers at the time.

27. Given that Penn Medicine's health care providers were in charge of the care of her newborn infant, Ms. Stills had no reason to doubt their word.

28. Additionally, the risk of necrotizing enterocolitis was not disclosed on the labeling or packaging of *any* of the Defendant Manufacturers' products.

29. What is more, necrotizing enterocolitis is a disease that can occur in children who are *not* fed the Defendant Manufacturers' products, and the Defendant Manufacturers have worked to mislead parents into a false sense of security about the use of those products. Publicly disseminated materials from each Defendant Manufacturer disguise the role their products play in causing the disease—and affirmatively say, even today, that their products are safe and do not cause NEC. In fact, some publicly disseminated materials from the formula manufacturers even suggest that formula may help *reduce* the risk of this terrible and potentially fatal disease.

30. For example, Abbott’s website stays that “[t]he specific cause of NEC is unknown, but it’s most often seen in very low birth weight premature babies,” and that “about 10% of babies who are born prematurely develop NEC.” The website suggests that “new preliminary studies” suggest for the first time that “NEC prevention may . . . be possible” with the use of human milk oligosaccharides to “dramatically curb intestinal inflammation” and reduce the risk of NEC. Abbott states that these human milk oligosaccharides are found in “certain Similac formulas” although they are “not currently available in Similac’s premature infant formulas.”¹ Likewise, the website for Mead Johnson’s products states that necrotizing enterocolitis is “one of the most common and serious intestinal disease[s] among premature babies.” And it deflects responsibility from Mead Johnson’s products: “Necrotizing enterocolitis happens when tissue in the small or large intestine is injured or inflamed.”²

31. Because of the misleading information distributed by the Defendant Manufacturers, as further detailed below, a reasonable person would not suspect that the Defendant Manufacturers’ products could have caused M.E.’s injuries.

32. Ms. Stills also did not know, and had no reason to know or suspect, that Penn Medicine breached its duty of care by distributing the Defendant Manufacturers’ products to him. Not only was Ms. Stills unaware that the Defendant Manufacturers’ products caused M.E.’s injuries, but the Defendant Manufacturers’ distribution agreements with Penn Medicine—which allowed Penn Medicine to secure sweetheart deals for otherwise expensive premature infant formula in exchange for product placement and access to the hospital staff—were also not public or knowable to Ms.

¹ The Role of HMOs in Reducing NEC, <https://www.nutritionnews.abbott/pregnancy-childhood/prenatal-breastfeeding/the-promising-role-of-hmos-in-reducing-risk-of-nec/> (last visited July 28, 2023).

² Special Feeding Concerns for Preemies, <https://www.enfamil.com/articles/special-feeding-concerns-for-preemies/> (last visited July 29, 2023).

Stills, nor could any reasonable investigation outside of litigation have uncovered the terms of those agreements.

Despite Exercising Reasonable Diligence, the Defendants' Fraudulently Concealed the Risks of NEC from Defendant Manufacturers' Products to Divert, Prevent, and Mislead Plaintiff Regarding the Cause of Her Child's NEC Diagnosis

33. In addition to the averments above, the Defendants have acted in concert to fraudulently convey false and misleading information concerning the risk of NEC, and potentially death, caused by Defendant Manufacturers' preterm infant formula products.

34. The Defendants' actions as set forth herein constitute knowing misrepresentation, omission, suppression, and concealment of material facts, made with the intent that Plaintiff would rely upon such concealment, suppression, or omission, in connection with the use of Defendants' preterm infant products.

35. Plaintiff did not know, and could not learn, the truth concerning the uses, risks and benefits of Defendant Manufacturers' preterm infant products due to Defendants' deliberate misrepresentations and concealment, suppression and omission of material facts and important information regarding the risks of NEC, and potentially death, from the products.

36. Moreover, Defendant Hospital further participated in the intentional concealment—on information and belief, it allowed the Defendant Manufacturers' sales representatives into its hospital to provide samples and free products that did not warn of their serious dangers, and to provide “education” to its NICU staff that was incomplete as to the true risks of feeding their patients the Defendant Manufacturers' products.

37. Additionally, Defendant Hospital failed to inform Ms. Stills that the Defendant Manufacturers' products caused Plaintiff's NEC. As noted above, after learning of Plaintiff's NEC diagnosis, Ms. Stills was understandably concerned about the degrading health of her newborn

infant. But even though Defendant Hospital knew of the increased risk of NEC from formula, it did not disclose that the formula provided to M.E. could increase the risk of NEC to preterm infants. Not one person at the NICU mentioned that the Defendant Manufacturers' formula products could have been the cause of Plaintiff's injuries.

38. Defendant Hospital was aware that the Defendant Manufacturers' products caused NEC in premature infants. Defendant Hospital was also aware that the Defendant Manufacturers did not provide warnings on their products. However, Defendant Hospital did not warn Ms. Taylor of the risks of the products. Instead, and notwithstanding the sweetheart deal Defendant Hospital agreed to in exchange for preterm infant formula at little to no cost, Defendant Hospital repeatedly informed Ms. Stills that it would do everything it could possibly do to keep her infant safe. Though this was clearly not true given the known risks of preterm formula for babies like M.E., it was enough for Ms. Stills to trust that Defendant Hospital was providing preterm formula in the best interest of her child.

39. Defendants' affirmative acts of fraud and concealment, as averred herein, diverted, prevented, and/or mislead Plaintiff from discovering the medical cause of her child's NEC diagnosis.

The Defendant Manufacturers' False and Misleading Marketing Regarding Cow's Milk-Based Infant Products

40. Abbott and Mead have aggressively marketed their cow's milk-based products as medically endorsed and nutritionally equivalent alternatives to breast milk, including prior to the Injured Infant's birth.

41. Abbott's and Mead's marketing approach includes targeting the parents of preterm infants while they are still in the hospital with messages that the Defendant Manufacturers' cow's milk formulas and fortifiers are necessary for the growth and development of their vulnerable children.

Often these tactics implicitly discourage mothers from breastfeeding, which reduces the mother's supply of breast milk. None of the Defendant Manufacturers' marketing materials, including their promotional websites, reference the science showing how significantly their products increase the risk of NEC.

42. Undoubtedly aware of the impact of their advertising, the Defendant Manufacturers, along with other formula manufacturers, are willing to spend massive sums to disseminate their message.

43. Recognizing the abuse and dangers of infant formula marketing, in 1981, the World Health Assembly—the decision-making body of the World Health Organization—developed the International Code of Marketing of Breast-milk Substitutes (“the Code”), which required companies to acknowledge the superiority of breast milk, the negative effect on breastfeeding of introducing partial bottle-feeding, and the difficulty of reversing the decision not to breastfeed. The Code also forbade advertising or other forms of promotion of formula to the general public, as well as providing sample products to mothers or members of their families.

44. While Abbott and Mead acknowledge the Code on their websites and claim to support the effort to encourage mothers to breastfeed for as long as possible, this is little more than lip service. Instead, the Defendant Manufacturers' aggressive marketing exploits new parents' darkest fears—that the nutrition they are supplying to their child will not provide the best chance of survival—while wholly failing to warn that their products come with a significantly increased risk of NEC.

45. For example, Abbott's website, on a page titled “Infant Formula Marketing,” states: “We agree with the World Health Organization that breastfeeding provides the best nutrition for babies, and we support its goal to increase breastfeeding. We also recognize that for infants who aren't breastfed—for medical reasons or otherwise—infant formula is the only appropriate, safe

alternative to meet babies' nutritional needs." This statement ignores the existence of donor milk, as well as human milk-based formula.

46. Abbott markets and sells multiple products specifically targeting preterm and low-birthweight infants, including Liquid Protein Fortifier, Similac NeoSure, Similac Human Milk Fortifiers, Similac Special Care 20, Similac Special Care 24, Similac Special Care 24 High Protein, and Similac Special Care 30. In advertising these products, Abbott emphasizes the products' purported ability to assist underdeveloped babies in reaching their growth targets. For example, on the since-edited webpage regarding Similac NeoSure, Abbott noted: "Your premature baby didn't get her full 9 months in the womb, so her body is working hard to catch up. During her first full year, feed her Similac NeoSure, a nutrient-enriched formula for babies who were born prematurely, and help support her development." Yet, no mention was made of the accompanying significantly increased risk of NEC. At some point, the website was edited to remove this statement. However, upon information and belief, the statement remained on the website until at least December 2020.

47. Mead markets and sells multiple products specifically targeting premature infants, including Enfamil NeuroPro EnfaCare Infant Formula, Enfamil Premature Infant Formula 24 Cal High Protein, Enfamil Premature Infant Formula 30 Cal with Iron, Enfamil Premature Infant Formula 24 Cal with Iron, Enfamil Premature Infant Formula 20 Cal with Iron, Enfamil 24 Cal Infant Formula, and Enfamil Human Milk Fortifier (acidified liquid and powder). In advertising these products, Mead emphasizes the purported similarities between its formula and breast milk, while failing to include any information about the nutritional deficits and dangers that accompany formula use. For example, the since-edited webpage for Enfamil Enfacare stated: "Premature babies fed Enfamil® formulas during the first year have achieved catch-up growth similar to that

of full term, breastfed infants” and noted that Enfamil formulas include “expert-recommended levels of DHA and ARA (important fatty acids found naturally in breast milk) to support brain and eye development.”

48. One Enfamil advertisement, introducing a new product line called Enfamil NeuroPro, is entirely focused on favorably comparing Enfamil’s formula to breast milk, without any mention of the product’s extreme risks. Indeed, the terms “human milk” and “breast milk” are used 13 times in the advertisement, including in such statements as “for decades human milk has inspired the advancements in Enfamil formulas and now through extensive global research, we are taking an even closer look at human milk” and “only Enfamil NeuroPro has a fat blend of MFGM and DHA previously found only in breast milk.” The webpage for the product has made similar manipulative claims, stating “Enfamil is backed by decades of breast milk research and multiple clinical studies” and it claims that “to create our best formulas, we collaborated on some of the most extensive breast milk studies to date[.]”

49. Formula manufacturers have long used their relationships with hospitals and the discharge process to encourage parents to substitute formula for breast milk. They offer free or reduced-cost formula to hospitals for use with infants before discharge. And they offer free formula, coupons, and even entire gift baskets to parents before their infants’ discharge from the NICU or hospital.

50. Through this early targeting, the Defendant Manufacturers create brand loyalty under the guise of a “medical blessing,” in hopes that new parents continue to use formula after they leave the hospital, resulting in increased expense for parents, significantly increased risk for babies, and increased profit for the Defendant Manufacturers. The Defendant Manufacturers’ giveaways and gift baskets send confusing signals to mothers who are simultaneously being encouraged to breastfeed by their healthcare professionals, and they have been shown to negatively impact

breastfeeding rates.

51. Further, when the Defendant Manufacturers recognized a shift in the medical community towards an exclusive breast milk-based diet for premature infants, Abbott developed a product called “Similac Human Milk Fortifier,” and Mead developed “Enfamil Human Milk Fortifier.” These names are misleading in that they suggest that the products are derived from breast milk, when, in fact, they are cow’s milk-based products. The packaging appears as:



52. The Defendant Manufacturers have designed powerful misleading marketing campaigns to deceive parents into believing that: (1) cow’s milk-based products are safe, including for preterm infants; (2) cow’s milk-based products are equal, or even superior, substitutes to breast milk; (3) cow’s milk-based products are necessary for proper growth and development of preterm infants; and (4) physicians consider the Defendant Manufacturers’ cow’s milk-based products to be a first

choice. This marketing scheme is employed despite all Defendants knowing of and failing to warn of the extreme risk of NEC and death that cow's milk-based products pose to preterm infants like the Injured Infant.

53. The Defendant Manufacturers have also designed powerful marketing campaigns to both the general public and health care providers at hospitals like Pennsylvania Hospital. The Defendant Manufacturers know that sales made to hospitals are key drivers of brand loyalty, and thus are a key opportunity to drive better downstream business—*i.e.*, retail purchases by parents after they have left the hospital. On information and belief, the Defendant Manufacturers know that the formula products used in a hospital's NICU are related to getting and keeping the overall hospital contracts. And the Defendant Manufacturers know that, just like any celebrity endorsement, when mothers of newborn infants see medical professionals using a certain brand, the mothers are more likely to continue to purchase that same brand after discharge. The Defendant Manufacturers are thus heavily motivated to ensure that NICU departments are using their products.

54. Abbott and Mead Johnson focus their sales teams and training heavily on hospital NICU departments. They train their sales representatives how to increase the number of babies on their formula, and they emphasize the need to be the dominant formula manufacturer in the NICU so they can own that profitable ground and secure a great return on their substantial investment in NICU formula and other products.

55. To leverage hospitals' NICUs and secure babies in the hospital and at retail, the Manufacturer Defendants pull out all the stops to convince hospitals, including Defendant Hospital, to purchase their products. For example: Abbott and Mead Johnson provide samples of their products to hospitals for free.

56. On information and belief, to get the hospitals on board with supplying their formula for premature infants, Abbott and Mead Johnson work with hospitals to secure contracts that have special pricing discounts if a certain level of the formula-fed babies in the hospital receive just that one manufacturer's products; similar to a restaurant being a Coke or Pepsi restaurant. And notwithstanding the increased risk of the Defendant Manufacturers' products for the hospitals' most fragile patients—the preterm infants—the decision makers at these hospitals seek out these types of contracts to better the hospitals' own bottom lines.

57. On information and belief, Abbott and Mead Johnson also seek promises and/or assurances that the full range of health care providers at the hospitals, including the nurse practitioners and other staff who would pull the infant formula off the shelf, are grabbing the respective company's own formula products to give to the preterm infants. The goal of this tactic was to ensure that the Defendant Manufacturers and key people at the hospital would be sending a shared message that the preterm infant formula products were safe and without risk, even though that is not what the science said.

58. Prior to M.E.'s birth, Abbott sent sales representatives to Defendant Hospital. Those sales representatives provided information about Abbott's products to Defendant Hospital's staff via conversations, presentations, and written pamphlets. This information indicated that Abbott's products were safe to give to preterm infants like M.E. Abbott maintains call logs that detail which sales representatives visited the hospitals, which days they visited, and which products they discussed. These sales representatives did not disclose that Abbott's products could cause NEC in preterm infants.

59. Prior to M.E.'s birth, Mead Johnson sent sales representatives to Defendant Hospital. Those sales representatives provided information about Mead Johnson's products to Defendant

Hospital's staff via conversations, presentations, and written pamphlets. This information indicated that Mead Johnson's products were safe to give to preterm infants like M.E. Mead Johnson maintains call logs that detail which sales representatives visited the hospitals, which days they visited, and which products they discussed. These sales representatives did not disclose that Mead Johnson's products could cause NEC in preterm infants.

60. Mead Johnson and Abbott believed and intended that the misrepresentations that its sale representatives shared with Defendant Hospital would be used to make feeding decisions for preterm infants like M.E.

The Defendant Manufacturers' Inadequate Warnings

61. Although Mead promotes an aggressive marketing campaign designed to convince parents that its cow's milk-based products are safe and necessary for the growth of a premature infant, the product is in fact extremely dangerous for premature infants. Enfamil products significantly increase the chances of a premature infant developing potentially fatal NEC.

62. The Enfamil products Mead markets specifically for premature infants are commercially available at retail locations and online. No prescription is necessary.

63. Despite knowing of the risk of NEC, the packaging of Mead's products does not warn of the significantly increased risk of NEC (and resulting medical conditions, and/or death) associated with Mead's products, or of the magnitude of this increased risk. Mead likewise did not provide instructions or guidance for how to avoid NEC.

64. Mead cites no medical literature or research to guide the use of its products.

65. Despite knowing of the risk of NEC, Mead did not warn of the significantly increased risk of NEC (and resulting medical conditions, and/or death) associated with its products, or of the magnitude of this increased risk. Mead likewise did not provide instructions or guidance for how to avoid NEC.

66. Mead deceived the public, parents, physicians, other medical professionals, and medical staff into believing that Enfamil products were a safe and necessary alternative, supplement and/or substitute to breast milk.

67. Mead Johnson failed to provide, and continues to fail to provide, a full accounting of the risk of NEC as documented, by underrepresenting and misrepresenting the risk to the public and the medical community.

68. Despite knowing that its products were being fed to premature infants, often without the parents' informed consent, Mead failed to require or recommend that medical professionals inform parents of the significant risk of NEC or to require that parental consent be obtained prior to the products being fed to their babies. Like Mead, Abbott promotes an aggressive marketing campaign designed to make parents believe that its products are safe and necessary for the growth of premature infants, despite the products in fact being extremely dangerous for premature infants. Abbott's products significantly increase the chances of a premature infant getting potentially fatal NEC.

69. The products Abbott markets specifically for premature infants are available at retail locations and online. No prescription is necessary.

70. Despite knowing of the risk of NEC, Abbott did not warn of the significantly increased risk of NEC (and resulting medical conditions, and/or death) associated with its products, or of the magnitude of this increased risk. Abbott likewise did not provide instructions or guidance for how to avoid NEC.

71. Abbott deceived the public, parents, physicians, other medical professionals, and medical staff into believing that its products were a safe and necessary alternative, supplement and/or substitute to breast milk.

72. Despite knowing of studies documenting an increased risk of NEC from its products, Abbott did not act to make parents or the medical community aware of those risks, and instead took steps to conceal or prevent those risks from becoming public. Despite knowing that its products were being fed to premature infants, often without the parents' informed consent, Abbott failed to require or recommend that medical professionals inform parents of the significant risk of NEC or to require that parental consent be obtained prior to the products being fed to their babies.

Penn Medicine's Failure to Warn

73. On information and belief, Penn Medicine, which operates Pennsylvania Hospital, was aware of the significantly increased risk of NEC and death associated with providing Abbott's and Mead's cow's milk-based products to its premature infant patients. It knew or should have known that feeding these cow's milk-based products can cause NEC in premature infants who otherwise would not have developed this devastating condition. However, instead of warning of the dangers, or supplying breast milk-based feeding products to preterm infants like the Injured Infant, Penn Medicine has continued to source, distribute, and supply the Defendant Manufacturers' products in its hospitals without any adequate warning.

74. To that end, Penn Medicine has participated in studies designed to increase the use of donor milk while, at the same time, reducing formula feeding in neonates. The University of Pennsylvania School of Nursing, an affiliate of Penn Medicine, has conducted extensive research into the risks associated with feeding formula to premature infants. It recently partnered with the National Institute of Nursing Research to publish clinical determinations based on its experience "changing hospital systems and influencing policy," and its findings were unequivocal:

This is what we know about the science of human milk: it reduces the risk of necrotizing enterocolitis, reduces the risk of infection, [and] creates greater enteral feed tolerance and more rapid weaning from intravenous nutrition. . . .

Other Penn Medicine research has similarly concluded that "[h]uman milk decreases the incidence

and severity of . . . necrotizing enterocolitis (NEC).”

75. Penn Medicine also purports to adhere to the tenets of the “Baby Friendly Hospital Initiative,” which seeks to increase rates of breastfeeding initiation, exclusivity, and diet duration. The “Baby Friendly Hospital Initiative” specifically targets a reduction in the rates of NEC in preterm infants by encouraging implementation of exclusive breast milk diets among new mothers. Although Pennsylvania Hospital has maintained its “Baby Friendly” designation for years, it has not eliminated or restricted the use of formula or fortifier for preterm infants in its hospitals.

76. Finally, medical providers and staff at Penn Medicine have acknowledged the risks associated with providing the Defendant Manufacturers’ cow’s milk-based products to premature infant patients instead of breast milk-based nutrition. In an internal newsletter from 2012 touting donor milk programs, Penn Medicine acknowledged the benefits of a human milk-based diet, quoting a staff lactation consultant:

Donor milk is not inexpensive. It costs about \$4.25 per ounce, but the return on investment is huge. “Preemies given mother’s milk get discharged three to four days sooner and also have a six to 10 times lower risk of getting a gastrointestinal complication called necrotizing enterocolitis,” Carpenter said, adding that the infection can cost up to \$250,000 to treat. The average cost to provide a preemie with donor milk: \$125.

77. These statements demonstrate that Penn Medicine knew or should have known of the high increased risk of NEC for premature infants posed by the Defendant Manufacturers’ products.

78. Although Penn Medicine knew or should have known of the serious danger of the Defendant Manufacturers’ products, it has continued to purchase, supply, and distribute these products to preterm infants without providing full and adequate warnings of the attendant risks to parents, healthcare professionals, and other medical staff at its relevant facilities. As a result, the Injured Infant was fed the Defendant Manufacturers’ cow’s milk-based products at Pennsylvania

Hospital, causing their injuries. This occurred even though hospitals across the country, including Pennsylvania Hospital, warn and obtain consent from parents before providing other safer forms of nutrition, such as donor breast milk.

79. Penn Medicine's failure to warn of the risks posed by the Defendant Manufacturers' products is entrenched (and compounded) by the financial benefits it accrues from its relationships with the Defendant Manufacturers. On information and belief, it has received the Defendant Manufacturers' cow's milk-based products for free and/or at a significant discount, and has granted their sales representatives access to its healthcare professionals and medical staff. These sales representatives have provided deceptive information that Penn Medicine reasonably knew or should have known would ultimately reach parents through those staff. This arrangement dovetails with the Defendant Manufacturers' own marketing strategies" and use of salespersons.

Safer Alternative Designs

80. The Defendant Manufacturers' cow's milk-based products made specifically for premature infants are unreasonably unsafe for those infants. The Defendant Manufacturers could have used pasteurized breast milk instead of cow's milk in their products, which would have produced a safer product.

81. Prolacta Bioscience manufactures and sells breast milk-based feeding products, specifically designed for preterm infants, which contain no cow's milk. This alternative design provides all the necessary nutrition for growth and development that cow's milk-based products provide, without the same unreasonably dangerous and deadly effects.

82. On information and belief, Abbott and Mead were aware of the significantly increased risk of NEC and death associated with their cow's milk-based products, and instead of warning of the dangers, or removing them altogether, Abbott and Mead have continued to use cow's milk as the

foundation of their products.

CAUSES OF ACTION
COUNT I: STRICT LIABILITY FOR DESIGN DEFECT
(Against Abbott and Mead)

83. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.

84. Abbott and Mead, as the manufacturers and/or sellers of the products at issue in this litigation, owed a duty to the consuming public in general, and the Plaintiff Parent in particular, to manufacture, sell, and distribute their products in a manner that was not unreasonably dangerous.

85. Abbott and Mead also owed a duty to the consuming public in general, and the Plaintiff Parent in particular, to manufacture, sell, and distribute their products in a manner that was merchantable and reasonably suited for their intended use.

86. Abbott and Mead knew that their products would be used to feed premature infants like the Injured Infant and knew (or reasonably should have known) that use of their cow's milk-based products significantly increased the risk of NEC, serious injury, and death, and that such use was therefore unreasonably dangerous to premature infants, not reasonably suited for the use intended, not merchantable, and had risks that exceeded a reasonable buyer's expectations. Nonetheless, they continued to sell and market their defective products as appropriate for premature infants.

87. The Injured Infant ingested Abbott and/or Mead's unreasonably dangerous cow's milk-based products. The risks of feeding those products to the Injured Infant outweighed the benefits. An ordinary consumer would not expect those products to carry a significant risk of serious injury and death from NEC.

88. Abbott and Mead knew (or reasonably should have known) that breast milk-based nutrition did not carry the same risks of NEC, serious injury, and death that their products do.

89. Abbott's and Mead's products contained cow's milk at the time they left the manufacturing facility.

90. Abbott and Mead did not develop a human-milk based product that was safer for premature infants and did not reformulate their products to reduce the risk of NEC, serious injury, and death, even though doing so was economically and technologically feasible and even though pasteurized breast milk was an available alternative.

91. Abbott's and/or Mead's products were fed to the Injured Infant, which caused and/or increased the risk of their NEC and injuries.

92. As a further direct result, the Plaintiff Parent suffered significant emotional distress, loss of income, and/or other harms. Her life has been significantly affected by the Injured Infant's injuries.

WHEREFORE, Plaintiff demands judgment against the Defendant Manufacturers, individually, jointly and severally, as follows:

- a. For compensatory damages in an amount to be proven at trial and in excess of \$50,000 and this Court's arbitrational limit;
- b. For damages for past, present, and future emotional distress, loss of enjoyment of life, pain and suffering, mental anguish, and other non-economic losses sustained as a result of the Defendants Manufacturers' conduct;
- c. For past, present, and future out-of-pocket costs, lost income and/or lost revenue, and/or lost profits, and/or lost business opportunity, lost earning capacity, and costs related to medical or mental health treatment which have or may be recommended;

- d. For punitive damages in excess of \$50,000 and this Court's arbitral limit resulting from the Defendant Manufacturers' oppressive, fraudulent, and/or malicious conduct, as permitted by law;
- e. For interest as permitted by law;
- f. For attorney's fees, expenses, and recoverable costs incurred in connection with this action; and
- g. For such other and further relief as the Court deems proper.

**COUNT II: STRICT LIABILITY FOR FAILURE TO WARN
(Against Abbott and Mead)**

93. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.

94. Abbott and Mead, as the manufacturers and/or sellers of the infant products at issue in this litigation, owed a duty to the consuming public in general, and the Plaintiff Parent in particular, to provide adequate warnings or instructions about the dangers and risks associated with the use of their products with preterm infants, specifically including but not limited to the risk of NEC, serious injury, and death.

95. Abbott's and Mead's duty to warn is part of their general duty to design, manufacture, and sell their infant products in a manner that is reasonably safe for their foreseeable uses. By designing their products with cow's milk-based ingredients, Abbott and Mead undertook a duty to warn of the unreasonable risk of harm posed by those ingredients, specifically including the significantly increased risk of NEC, severe injury, and death. The failure to warn makes the products at issue in this litigation unreasonably dangerous.

96. Specifically, Abbott and Mead breached their duty to warn of the foreseeable risks of the infant products at issue in this litigation because they knew or should have known that their

cow's milk-based premature infant products would be fed to premature infants like the Injured Infant, and that their products might cause the Injured Infant to develop NEC, severe injury, or death, yet they failed to provide adequate warnings of those risks. Among other risks, the Defendant Manufacturers:

- a. Failed to warn that cow's milk-based products significantly increase the risk of NEC, severe injury, and death for the Injured Infant; and/or
- b. Failed to warn that cow's milk-based products are unsafe and/or contraindicated for premature infants like the Injured Infant; and/or
- c. Inserted warnings and instructions on their products that are severely inadequate, vague, confusing, and provide a false sense of security in that they warn and instruct specifically on certain conditions, but do not warn of the significantly increased risk of NEC and death; and/or
- d. "Black box"-type warning that their cow's milk-based products are known to significantly increase the risk of NEC and death when compared to breast milk in premature infant; and/or
- e. Failed to disclose well-researched and well-established studies that linked cow's milk-based products to NEC and death in premature infants; and/or
- f. Failed to insert a warning or instruction to healthcare professionals and other medical staff in the hospital that parents should be provided information necessary to make an informed choice about whether to allow their babies to be fed the Defendant Manufacturers' products, notwithstanding their substantial risks; and/or
- g. Failed to provide a warning in a method reasonably calculated or expected

to reach the parents of newborns, like the Plaintiff Parent; and/or

- h. Failed to provide statistical evidence showing the magnitude of increased risk of NEC in premature infants associated with cow's milk-based products.

97. Abbott's and Mead's products contained cow's milk at the time they left the manufacturing facility.

98. As a direct and proximate result of the inadequacy of the warnings and the pervasive marketing campaigns suggesting the safety and necessity of the Defendant Manufacturers' products, the Injured Infant were fed cow's milk-based products, which caused and/or increased risk of their developing NEC.

99. The unwarned-of risks are not of a kind that an ordinary consumer would expect. Had physicians and medical staff known of the extreme risk associated with feeding premature infants cow's milk-based formula, they would not have fed the Injured Infant those products. Had the Plaintiff Parent known of the significant risks of feeding the Injured Infant cow's milk-based formula, they would not have allowed such products to be fed to the Injured Infant.

100. As a further direct result, the Plaintiff Parent suffered significant emotional distress, loss of income, and/or other harms. Her life has been significantly affected by the Injured Infant's injuries.

WHEREFORE, Plaintiff demands judgment against the Defendant Manufacturers, individually, jointly and severally, as follows:

- a. For compensatory damages in an amount to be proven at trial and in excess of \$50,000 and this Court's arbitrational limit;
- b. For damages for past, present, and future emotional distress, loss of

enjoyment of life, pain and suffering, mental anguish, and other non-economic losses sustained as a result of the Defendants Manufacturers' conduct;

- c. For past, present, and future out-of-pocket costs, lost income and/or lost revenue, and/or lost profits, and/or lost business opportunity, lost earning capacity, and costs related to medical or mental health treatment which have or may be recommended;
- d. For punitive damages in excess of \$50,000 and this Court's arbitral limit resulting from the Defendants Manufacturers' oppressive, fraudulent, and/or malicious conduct, as permitted by law;
- e. For interest as permitted by law;
- f. For attorney's fees, expenses, and recoverable costs incurred in connection with this action; and
- g. For such other and further relief as the Court deems proper.

**COUNT III: NEGLIGENCE
(Against Abbott and Mead)**

101. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.

102. Abbott and Mead, as the manufacturers and/or sellers of the products at issue in this litigation, owed a duty to the consuming public in general, and the Plaintiff Parent in particular, to exercise reasonable care to design, test, manufacture, inspect, and distribute a product free of unreasonable risk of harm to users, when such products are used in their intended manner and for their intended purpose.

103. At all times relevant to this action, the Injured Infant's healthcare professionals and medical

staff used the products at issue in their intended manner and for their intended purpose.

104. Abbott and Mead, directly or indirectly, negligently, and/or defectively made, created, manufactured, designed, assembled, tested, marketed, sold, and/or distributed the cow's milk-based infant products at issue in this litigation and thereby breached their duty to the general public and the Plaintiff Parent.

105. Specifically, although Abbott and Mead knew or reasonably should have known at the time of production that their cow's milk-based infant products significantly increased the risk of NEC, serious injury, and death, they failed to act in a reasonably prudent manner and breached their duty by:

- a. Failing to warn that cow's milk-based products significantly increase the risk of NEC, severe injury, and death for the Injured Infant; and/or
- b. Failing to warn that cow's milk-based products are unsafe and/or contraindicated for premature infants like the Injured Infant; and/or
- c. Inserting warnings and instructions that are severely inadequate, vague, confusing, and provide a false sense of security in that they warn and instruct specifically on certain conditions, but do not warn of the significantly increased risk of NEC and death; and/or
- d. Failing to insert a large and prominent "black box"-type warning that their cow's milk-based products are known to significantly increase the risk of NEC and death when compared to breast milk in premature infants; and/or
- e. Failing to provide well-researched and well-established studies that linked cow's milk-based products to NEC and death in premature infants; and/or
- f. Failing to insert a warning or instruction to healthcare professionals and

other medical staff in the hospital that parents should be provided information necessary to make an informed choice about whether to allow their babies to be fed the Defendant Manufacturers' products, notwithstanding their substantial risks; and/or

- g. Failing to provide a warning in a method reasonably calculated/expected to reach the parents of newborns, like the Plaintiff Parent; and/or
- h. Failing to provide statistical evidence showing the magnitude of increased risk of NEC in premature infants associated with cow's milk-based products.

106. In addition, although Abbott and Mead knew or reasonably should have known at the time of production that their cow's milk-based products significantly increased the risk of NEC, serious injury, and death, they failed to act in a reasonably prudent manner and breached their duty by failing to perform the necessary process of data collection, detection, assessment, monitoring, prevention, and reporting or disclosure of adverse outcomes in infants who ingest their products.

107. As a direct and proximate result of the Defendant Manufacturers' failure to act in a reasonably prudent manner and their breach of duty, the Injured Infant was fed cow's milk-based products, which caused and/or increased the risk of their developing NEC.

108. Had Abbott and Mead satisfied their duties to the consuming public in general, the Injured Infant would not have been exposed to their unreasonably dangerous cow's milk-based products.

109. As a further direct result, the Plaintiff Parent suffered significant emotional distress, loss of income, and/or other harms. Her life has been significantly affected by the Injured Infant's injuries.

WHEREFORE, Plaintiff demands judgment against the Defendant Manufacturers,

individually, jointly and severally, as follows:

- a. For compensatory damages in an amount to be proven at trial and in excess of \$50,000 and this Court's arbitrational limit;
- b. For damages for past, present, and future emotional distress, loss of enjoyment of life, pain and suffering, mental anguish, and other non-economic losses sustained as a result of the Defendants Manufacturers' conduct;
- c. For past, present, and future out-of-pocket costs, lost income and/or lost revenue, and/or lost profits, and/or lost business opportunity, lost earning capacity, and costs related to medical or mental health treatment which have or may be recommended;
- d. For punitive damages in excess of \$50,000 and this Court's arbitrational limit resulting from the Defendants Manufacturers' oppressive, fraudulent, and/or malicious conduct, as permitted by law;
- e. For interest as permitted by law;
- f. For attorney's fees, expenses, and recoverable costs incurred in connection with this action; and
- g. For such other and further relief as the Court deems proper.

**COUNT IV: INTENTIONAL MISREPRESENTATION
(Against Abbott and Mead)**

110. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.

111. At all times relevant to this action, the Injured Infant consumed the Defendant Manufacturers' products in their intended manner and for their intended purpose.

112. Abbott and Mead, as the manufacturers and/or sellers of the infant products at issue in this litigation, owed a duty to the consuming public in general, and the Plaintiff Parent in particular, to provide truthful, accurate, fulsome information about the risks and benefits of using their products when used in the intended manner and for the intended purpose.

113. Abbott and Mead breached their duty through misrepresentations made to consumers, physicians, and medical staff in their advertising and promotional materials, as described in previous paragraphs and incorporated herein, each of whom were foreseeable and intended recipients of this information.

114. Specifically, upon information and belief, Abbott and Mead made the following false statements of material fact on an ongoing and repeated basis and prior to the time the Injured Infant was fed their products:

- a. That their cow's milk-based products were safe and beneficial for premature infants when they knew or should have known that their products were unreasonably dangerous and cause NEC, serious injury, and death in premature infants; and/or
- b. That their cow's milk-based products were necessary to the growth and nutrition of premature infants, when they knew or should have known that their products were not necessary to achieve adequate growth; and/or
- c. That their products have no serious side effects, when they knew or should have known the contrary to be true; and/or
- d. That cow's milk-based products were safe for premature infants; and/or
- e. That cow's milk-based products were necessary for optimum growth; and/or
- f. That cow's milk-based products were similar or equivalent to breast milk;

and/or

- g. That their products were safe and more like breast milk than other infant products and that they had removed the harmful ingredients of cow's milk when, in fact, the cow's milk in their products was still capable of causing NEC, serious injury, and death; and/or
- h. That their products were based on up-to-date science, which made them safe for premature infants; and/or
- i. Omitting the material fact that their products significantly increased the risk of NEC in premature infants.

115. Abbott and Mead had actual knowledge, or, at a minimum, a reckless indifference, to whether the aforementioned misrepresentations were false. The Defendant Manufacturers' misrepresentations were intended to, and in fact did, mislead physicians and medical staff, including the Injured Infant's physicians and medical staff, to provide their infant products to babies, including the Injured Infant.

116. The Plaintiff Parent was not aware that these misrepresentations were false and justifiably relied on them. The Defendant Manufacturers' misrepresentations induced the Plaintiff Parent to allow their children to be fed Abbott's and Mead's infant products, in reliance on all the messaging they received about formula feeding, including, directly or indirectly, the Defendant Manufacturers' messaging. Had Abbott and Mead not committed these intentional misrepresentations, the Injured Infant would not have been exposed to the Defendant Manufacturers' unreasonably dangerous cow's milk-based products.

117. As a direct and proximate result, Abbott's and Mead's products were fed to the Injured Infant, which caused and/or increased risk of their developing NEC and subsequent injuries.

118. As a further direct result, the Plaintiff Parent suffered significant emotional distress, loss of income, and/or other harms. Her life has been significantly affected by the Injured Infant's injuries.

WHEREFORE, Plaintiff demands judgment against the Defendant Manufacturers, individually, jointly and severally, as follows:

- a. For compensatory damages in an amount to be proven at trial and in excess of \$50,000 and this Court's arbitrational limit;
- b. For damages for past, present, and future emotional distress, loss of enjoyment of life, pain and suffering, mental anguish, and other non-economic losses sustained as a result of the Defendants Manufacturers' conduct;
- c. For past, present, and future out-of-pocket costs, lost income and/or lost revenue, and/or lost profits, and/or lost business opportunity, lost earning capacity, and costs related to medical or mental health treatment which have or may be recommended;
- d. For punitive damages in excess of \$50,000 and this Court's arbitrational limit resulting from the Defendant Manufacturers' oppressive, fraudulent, and/or malicious conduct, as permitted by law;
- e. For interest as permitted by law;
- f. For attorney's fees, expenses, and recoverable costs incurred in connection with this action; and
- g. For such other and further relief as the Court deems proper.

**COUNT V: NEGLIGENT MISREPRESENTATIONS
(Against Abbott and Mead)**

119. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.

120. At all times relevant to this action, the Injured Infant consumed the products at issue in their intended manner and for their intended purpose.

121. Abbott and Mead, as the manufacturers and/or sellers of the products at issue in this litigation, owed a duty to the consuming public in general, and the Plaintiff Parent in particular, to provide truthful, accurate, and complete information about the risks and benefits of using their products when used in the intended manner and for the intended purpose.

122. In the course of their business, Abbott and Mead breached their duty through misrepresentations made to consumers, physicians, and medical staff in their advertising and promotional materials, as described in previous paragraphs and incorporated herein, each of whom were foreseeable recipients of this information.

123. Specifically, upon information and belief, Abbott and Mead made the following false statements of material fact on an ongoing and repeated basis and prior to the time the Injured Infant was fed their products:

- a. That their cow's milk-based products were safe and beneficial for premature infants when they knew or should have known that their products were unreasonably dangerous and cause NEC, serious injury, and death in premature infants; and/or
- b. That their cow's milk-based products were necessary to the growth and nutrition of premature infants, when they knew or should have known that their products were not necessary to achieve adequate growth; and/or
- c. That their products have no serious side effects, when they knew or should

have known the contrary to be true; and/or

- d. That cow's milk-based products were safe for premature infants; and/or
- e. That cow's milk-based products were necessary for optimum growth; and/or
- f. That cow's milk-based products were similar or equivalent to breast milk; and/or
- g. That their products were safe and more like breast milk than other infant products and that they had removed the harmful ingredients of cow's milk when, in fact, the cow's milk in their products was still capable of causing NEC, serious injury, and death; and/or
- h. That their products were based on up-to-date science, which made them safe for premature infants; and/or
- i. Omitting the material fact that their products significantly increased the risk of NEC in premature infants.

124. Abbott and Mead were negligent or careless in not determining those representations to be false.

125. The Defendant Manufacturers' misrepresentations were intended to and did in fact induce physicians and medical staff, including the Injured Infant's physicians and medical staff, to provide their products to babies, including the Injured Infant.

126. The Defendant Manufacturers' misrepresentations induced, and were intended to induce, the Plaintiff Parent to allow their child to be fed Abbott's and Mead's infant products, in justifiable reliance on all the messaging they received about formula feeding, including, directly or indirectly, the Defendant Manufacturers' messaging. Had Abbott and Mead not committed these negligent misrepresentations, the Injured Infant would not have been exposed to their unreasonably

dangerous cow's milk-based products.

127. As a direct and proximate result, Abbott's and Mead's products were fed to the Injured Infant, which caused and/or increased of their developing NEC and subsequent injuries.

128. As a further direct result, the Plaintiff Parent suffered significant emotional distress, loss of income, and/or other harms. Her life has been significantly affected by the Injured Infant's injuries.

WHEREFORE, Plaintiff demands judgment against the Defendant Manufacturers, individually, jointly and severally, as follows:

- a. For compensatory damages in an amount to be proven at trial and in excess of \$50,000 and this Court's arbitrational limit;
- b. For damages for past, present, and future emotional distress, loss of enjoyment of life, pain and suffering, mental anguish, and other non-economic losses sustained as a result of the Defendants Manufacturers' conduct;
- c. For past, present, and future out-of-pocket costs, lost income and/or lost revenue, and/or lost profits, and/or lost business opportunity, lost earning capacity, and costs related to medical or mental health treatment which have or may be recommended;
- d. For punitive damages in excess of \$50,000 and this Court's arbitrational limit resulting from the Defendant Manufacturers' oppressive, fraudulent, and/or malicious conduct, as permitted by law;
- e. For interest as permitted by law;
- f. For attorney's fees, expenses, and recoverable costs incurred in connection

with this action; and

- g. For such other and further relief as the Court deems proper.

**COUNT VI: FAILURE TO WARN
(Against Penn Medicine and Pennsylvania Hospital)**

129. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.

130. Penn Medicine and Pennsylvania Hospital as purchaser, supplier, and/or distributor of the products at issue in this litigation, owed a duty to the consuming public in general, and the Plaintiff Parent in particular, to purchase, supply, and distribute products that were free of unreasonable risk of harm when used in their intended manner and for their intended purpose, and/or to formulate, adopt, and enforce adequate rules and policies for the same.

131. At all times relevant to this action, the Injured Infant used the cow's milk-based products purchased, supplied, and/or distributed by Penn Medicine and Pennsylvania Hospital in their intended manner and for their intended purpose.

132. Penn Medicine and Pennsylvania Hospital employed or contracted with the healthcare professionals and medical staff at Pennsylvania Hospital, managing these individuals during their treatment of the Injured Infant.

133. Penn Medicine and Pennsylvania Hospital negligently, outrageously, and recklessly supplied and distributed the Defendant Manufacturers' milk-based infant feeding products to these healthcare professionals and medical staff for use on premature infants, including the Injured Infant.

134. Moreover, at all relevant times, Penn Medicine and Pennsylvania Hospital knowingly authorized the Defendant Manufacturers' sales representatives to market, advertise, distribute, and/or sell their products at Pennsylvania Hospital. The Defendant Manufacturers' sales

representatives were encouraged to interact with Pennsylvania Hospital's healthcare professionals and medical staff. These interactions provided the Defendant Manufacturers' sales representatives an opportunity to co-opt Pennsylvania Hospital's healthcare professionals and medical staff into assisting with the marketing, distribution, and/or sale of the Defendant Manufacturers' unreasonably dangerous products to consumers, such as the Plaintiff Parent.

135. Penn Medicine and Pennsylvania also knowingly, and intentionally, allowed the Defendant Manufacturers' sales representatives to routinely misrepresent the risks and benefits of Defendants' products to Pennsylvania Hospital's healthcare professionals and medical staff, including the misrepresentation that premature babies would not grow adequately with human milk and human milk products and that use of donor milk was not advised for premature infants.

136. Penn Medicine and Pennsylvania Hospital knew or reasonably should have known at the time that they acquired, distributed, and supplied the Defendant Manufacturers' cow's milk-based infant products that these products significantly increased the risk of NEC, serious injury, and death.

137. Nonetheless, Penn Medicine and Pennsylvania Hospital acted negligently, outrageously, and recklessly, and breached its duty by:

- a. Failing to warn that cow's milk-based products significantly increase the risk of NEC, severe injury, and death in those babies; and/or
- b. Failing to warn that cow's milk-based products are unsafe and/or contraindicated for premature infants like the Injured Infant; and/or
- c. Failing to warn or instruct its healthcare professionals and medical staff on the information that should be provided to parents in order to make an informed choice about whether to allow their babies to be fed the Defendant

Manufacturers' products, notwithstanding their substantial risk; and/or

- d. Failing to provide its healthcare professionals and medical staff with the well- researched and well-established studies that link cow's milk-based products to NEC and death in premature infants; and/or
- e. Failing to provide a warning in a method reasonably calculated/expected to reach the parents of newborns; and/or
- f. Failing to provide statistical evidence showing the magnitude of increased risk of NEC in premature infants associated with cow's milk-based products; and/or
- g. Failing to prevent the Defendant Manufacturers' sales representatives from misrepresenting to Pennsylvania Hospital's healthcare professionals and medical staff that premature babies would not grow adequately with human milk and human milk products and that use of donor milk was not advised for premature infants.

138. Reasonable hospitals under the same or similar circumstances would have warned of the above risks, would have instructed their healthcare professionals and medical staff—as well as patients—on the safe use of the Defendant Manufacturers' products, and would have restricted the ability of the Defendant Manufacturers' sales representatives to market the Defendant Manufacturers' unreasonably dangerous products without adequate warning.

139. Penn Medicine and Pennsylvania Hospital knew or reasonably should have known that its medical professionals and the parents of premature infants, including the Plaintiff Parent, would not have realized the risks associated with feeding cow's milk-based formula to premature infants.

140. Had Penn Medicine and Pennsylvania Hospital exercised reasonable care by satisfying its

duty to warn its medical providers and patients about the Defendant Manufacturers' unreasonably dangerous products, the Injured Infant would not have been exposed to the Defendant Manufacturers' cow's milk-based products.

141. As a direct and proximate result of Penn Medicine and Pennsylvania Hospital's failure to warn of the danger posed by the Defendant Manufacturers' unreasonably dangerous cow's milk-based products, the Injured Infant was fed the Defendant Manufacturers' cow's milk-based products, which caused and/or increased the risk of developing NEC and significant injuries.

142. As a further direct and proximate result of Penn Medicine and Pennsylvania Hospital's failure to warn of the Defendant Manufacturers' unreasonably dangerous products, the Plaintiff Parent suffered significant emotional distress, loss of income, and/or other harms. Her life has been significantly affected by the Injured Infant's injuries.

WHEREFORE, Plaintiff demands judgment against Penn Medicine and Pennsylvania Hospital, individually, jointly and severally, as follows:

- a. For compensatory damages in an amount to be proven at trial and in excess of \$50,000 and this Court's arbitrational limit;
- b. For damages for past, present, and future emotional distress, loss of enjoyment of life, pain and suffering, mental anguish, and other non-economic losses sustained as a result of Penn Medicine's conduct;
- c. For past, present, and future out-of-pocket costs, lost income and/or lost revenue, and/or lost profits, and/or lost business opportunity, lost earning capacity, and costs related to medical or mental health treatment which have or may be recommended;
- d. For punitive damages in excess of \$50,000 and this Court's arbitrational

limit resulting from Penn Medicine and Pennsylvania Hospital's oppressive, outrageous, reckless, and/or malicious conduct, as permitted by law;

- e. For interest as permitted by law;
- f. For attorney's fees, expenses, and recoverable costs incurred in connection with this action; and
- g. For such other and further relief as the Court deems proper.

**COUNT VII: CORPORATE LIABILITY OF HEALTH-CARE PROVIDER
(Against Penn Medicine and Pennsylvania Hospital)**

143. Plaintiff incorporates by references each of the preceding paragraphs as if fully set forth herein.

144. At all relevant times, Penn Medicine and Pennsylvania Hospital owed a duty of care to the Injured Infant to ensure their safety and well-being while the Injured Infant was under the care of Pennsylvania Hospital staff. Specifically, Penn Medicine and Pennsylvania Hospital had a duty to the Injured Infant to formulate, adopt, and enforce adequate rules and policies to ensure quality care for the Injured Infant. Further, Penn Medicine and Pennsylvania Hospital owed a duty to the Injured Infant to oversee its healthcare professionals and medical staff that provided patient care to the Injured Infant.

145. Penn Medicine and Pennsylvania Hospital owed a duty to its patients, and the Injured Infant in particular, to formulate, adopt, and enforce adequate rules and policies for the purchase, supply, distribution, and use of products that were free of unreasonable risk of harm when used in their intended manner and for their intended purpose and ensured quality care for the Injured Infant.

146. At all times relevant to this action, the Injured Infant used the cow's milk-based products purchased, supplied, and/or distributed by Penn Medicine and Pennsylvania Hospital in their

intended manner and for their intended purpose.

147. Moreover, at all relevant times, Penn Medicine and Pennsylvania Hospital knowingly authorized the Defendant Manufacturers' sales representatives to market, advertise, distribute, and/or sell their products at Pennsylvania Hospital. The Defendant Manufacturers' sales representatives were encouraged to interact with Pennsylvania Hospital's healthcare professionals and medical staff. These interactions provided the Defendant Manufacturers' sales representatives an opportunity to co-opt Pennsylvania Hospital's healthcare professionals and medical staff into assisting with the marketing, distribution, and/or sale of the Defendant Manufacturers' unreasonably dangerous products.

148. Penn Medicine and Pennsylvania Hospital also knowingly allowed the Defendant Manufacturers' sales representatives to routinely misrepresent the risks and benefits of Defendants' products to Pennsylvania Hospital's healthcare professionals and medical staff, including the misrepresentation that premature babies would not grow adequately with human milk and human milk products and that use of donor milk was not advised for premature infants.

149. Penn Medicine and Pennsylvania Hospital knew or reasonably should have known at the time that it formulated, adopted, and enforced its rules for the acquisition, distribution, and supply of the Defendant Manufacturers' cow's milk-based infant products, including the access afforded the Defendant Manufacturer's sales representatives, that these products significantly increased the risk of NEC, serious injury, and death for premature infants.

150. Penn Medicine and Pennsylvania Hospital knew or reasonably should have known that its medical professionals and the parents of premature infants, including the Plaintiff Parent, would not have realized the risks associated with feeding cow's milk-based formula to premature infants.

151. Nonetheless, Penn Medicine and Pennsylvania Hospital acted negligently, outrageously,

and recklessly, and breached its duty by:

- a. Failing to formulate, adopt, and enforce adequate rules and policies that would have restricted the use of cow's milk-based products for feeding premature babies; and/or
- b. Failing to formulate, adopt, and enforce adequate rules and policies that warned the Plaintiff Parent that cow's milk-based products significantly increase the risk of NEC, severe injury, and death in premature babies, like the Injured Infant; and/or
- c. Failing to formulate, adopt, and enforce adequate rules and policies that warned its healthcare professionals and medical staff that cow's milk-based products are unsafe and/or contraindicated for premature babies like the Injured Infant; and/or
- d. Failing to formulate, adopt, and enforce adequate rules and policies to instruct its healthcare professionals and medical staff on the information that should be provided to parents in order to make an informed choice about whether to allow their babies to be fed the Defendant Manufacturers' products, notwithstanding their substantial risk; and/or
- e. Failing to formulate, adopt, and enforce adequate rules and policies to provide its healthcare professionals and medical staff with the well-researched and well-established studies that link cow's milk-based products to NEC and death in premature infants; and/or
- f. Failing to formulate, adopt, and enforce adequate rules and policies to ensure a warning in a method reasonably calculated/expected to reach the

parents of newborns, like the Plaintiff Parent; and/or

- g. Failing to formulate, adopt, and enforce adequate rules and policies to prevent the Defendant Manufacturers' sales representative from misrepresenting to Pennsylvania Hospital's healthcare professionals and medical staff that premature babies would not grow adequately with human milk and human milk products and that use of donor milk was not advised for premature infants; and/or
- h. Failing to establish a donor milk program that was sufficient to meet the needs of the premature babies, like the Injured Infant.

152. A reasonable hospital under the same or similar circumstances would have formulated, adopted, and enforced adequate policies, and rules to restrict the feeding of cow's milk-based products to premature babies, including developing an adequate donor milk program, instructing its healthcare professionals and medical staff on the safe use of Defendants Manufacturers' cow's milk-based products, and restricting the marketing of the Defendant Manufacturers' unreasonably dangerous products to its healthcare professionals, medical staff, and parents of premature infants under its care.

153. Had Penn Medicine and Pennsylvania Hospital exercised reasonable care by satisfying its duty to formulate, adopt, and enforce adequate rules and policies to ensure the quality care of its patients, the Injured Infant would not have been exposed to the Defendant Manufacturers' cow's milk-based products.

154. As a direct and proximate result of Penn Medicine and Pennsylvania Hospital failure to formulate and enforce adequate policies and rules related to the danger posed by the Defendant Manufacturers' unreasonably dangerous cow's milk-based products, the Injured Infant was fed the

Defendant Manufacturers' cow's milk-based products, which caused and/or increased the risk of developing NEC and significant injuries.

155. As a further direct and proximate result of Penn Medicine and Pennsylvania Hospital negligent, reckless, and outrageous conduct the Plaintiff Parent suffered significant emotional distress, loss of income, and/or other harms. Her life has been significantly affected by the Injured Infant's injuries.

156. In the alternative, Penn Medicine and Pennsylvania Hospital owed a duty to its patients, and the Injured Infant in particular, to oversee the practicing healthcare professionals and medical staff that provided the products at issue to infants under Pennsylvania Hospital's care, including the Injured Infant.

157. Penn Medicine and Pennsylvania Hospital employed or contracted with the healthcare professionals and medical staff at Pennsylvania Hospital and was responsible for overseeing those individuals during their treatment of the Injured Infant.

158. Nonetheless, Penn Medicine and Pennsylvania Hospital acted negligently, recklessly, and outrageously breached its duty by:

- a. Failing to oversee its healthcare professionals and medical staff on their use of cow's milk-based products for feeding premature babies; and/or
- b. Failing to warn or instruct its healthcare professionals and medical staff that cow's milk-based products significantly increase the risk of NEC, severe injury, and death in those babies; and/or
- c. Failing to warn or instruct its healthcare professionals and medical staff that cow's milk-based products are unsafe and/or contraindicated for premature babies like the Injured Infant; and/or

- d. Failing to oversee its healthcare professionals and medical staff to restrict their feeding of cow's milk-based products to premature babies; and/or
- e. Failing to warn or instruct its healthcare professionals and medical staff on the information that should be provided to parents in order to make an informed choice about whether to allow their babies to be fed the Defendant Manufacturers' products, notwithstanding their substantial risk; and/or
- f. Failing to provide its healthcare professionals and medical staff with the well- researched and well-established studies that link cow's milk-based products to NEC and death in premature infants; and/or
- g. Failing to provide its healthcare professionals and medical staff with warnings about the dangers of the Defendants' Manufacturers products in a method reasonably calculated/expected to reach the parents of newborns; and/or
- h. Failing to provide statistical evidence to its healthcare professionals and medical staff showing the magnitude of increased risk of NEC in premature infants associated with cow's milk-based products; and/or
- i. Failing to oversee its healthcare professionals and medical staff to ensure that the Defendant Manufacturers' sales representatives' misrepresentations that premature babies would not grow adequately with human milk and human milk products and that use of donor milk was not advised for premature infants had not influenced the use and/or misuse of the Defendant Manufacturers' products.

159. A reasonable hospital under the same or similar circumstances would have warned of the

above risks, would have instructed its healthcare professionals and medical staff on the safe use of the Defendant Manufacturers' products, and would have restricted the ability of the Defendant Manufacturers' sales representatives to market the Defendant Manufacturers' unreasonably dangerous products without adequate warning.

160. A reasonable hospital under the same or similar circumstances would have overseen and managed its healthcare professionals and medical staff to ensure that they received proper training and updating on the risks associated with feeding cow's milk-based formula to premature infants.

161. Had Penn Medicine and Pennsylvania Hospital exercised reasonable care by satisfying its duty to oversee its healthcare professionals and medical staff who provide patient care, the Injured Infant would not have been exposed to the Defendant Manufacturers' cow's milk-based products.

162. As a direct and proximate result of Penn Medicine and Pennsylvania Hospital's failure to oversee its healthcare professionals and medical staff on the danger posed by the Defendant Manufacturers' unreasonably dangerous cow's milk-based products, the Injured Infant was fed the Defendant Manufacturers' cow's milk-based products, which caused and/or increased the risk of developing NEC and significant injuries.

163. As a further direct and proximate result of Penn Medicine and Pennsylvania Hospital's negligent and reckless conduct, the Plaintiff Parent suffered significant emotional distress, loss of income, and/or other harms. Her life has been significantly affected by the Injured Infant's injuries.

WHEREFORE, Plaintiff demands judgment against Penn Medicine and Pennsylvania Hospital, individually, jointly and severally, as follows:

- a. For compensatory damages in an amount to be proven at trial and in excess of \$50,000 and this Court's arbitrational limit;

- b. For damages for past, present, and future emotional distress, loss of enjoyment of life, pain and suffering, mental anguish, and other non-economic losses sustained as a result of Penn Medicine and Pennsylvania Hospital's conduct;
- c. For past, present, and future out-of-pocket costs, lost income and/or lost revenue, and/or lost profits, and/or lost business opportunity, lost earning capacity, and costs related to medical or mental health treatment which have or may be recommended;
- d. For punitive damages in excess of \$50,000 and this Court's arbitrational limit resulting from Penn Medicine's oppressive, fraudulent, and/or malicious conduct, as permitted by law;
- e. For interest as permitted by law;
- f. For attorney's fees, expenses, and recoverable costs incurred in connection with this action; and
- g. For such other and further relief as the Court deems proper.

DEMAND FOR JURY TRIAL

164. Plaintiff hereby demands a jury trial for all claims triable.

Dated: 9/8/2023

Respectfully submitted,

KLINE & SPECTER, P.C.

By: /s/ Timothy A. Burke
Thomas R. Kline, Esq.
Tobias L. Millrood, Esq.
Elizabeth A. Crawford, Esq.
Timothy A. Burke, Esq.
John P. O'Neill, Esq.

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EXHIBIT A-41

Alice Stills, on her own behalf and as Parent and Natural
Guardian of M.E., a minor

Plaintiffs

v.

MEAD JOHNSON & COMPANY, LLC, et al.

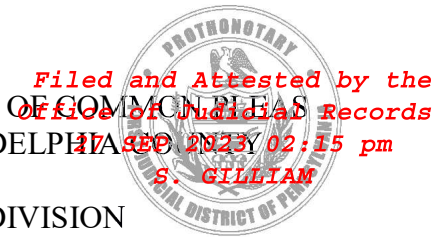
Defendants.

COURT OF COMMON PLEAS
PHILADELPHIA

CIVIL DIVISION

MARCH TERM, 2022

NO. 2617



ORDER

AND NOW, this day of 2023, upon consideration of the Preliminary Objections of Defendants The Pennsylvania Hospital of the University of Pennsylvania Health System d/b/a Pennsylvania Hospital and The Trustees of the University of Pennsylvania d/b/a Penn Medicine to Plaintiffs' Amended Complaint, and any Response thereto, it is hereby **ORDERED** that the Preliminary Objections are **SUSTAINED**. It is further **ORDERED** that all claims against Defendants the Pennsylvania Hospital of the University of Pennsylvania Health System d/b/a Pennsylvania Hospital and The Trustees of the University of Pennsylvania d/b/a Penn Medicine are hereby **DISMISSED** with prejudice.

BY THE COURT:

J.

Alice Stills, on her own behalf and as Parent
and Natural Guardian of M.E., a minor

Plaintiffs

v.

MEAD JOHNSON & COMPANY, LLC, et
al.

Defendants.

COURT OF COMMON PLEAS
PHILADELPHIA COUNTY

CIVIL DIVISION

MARCH TERM, 2022
NO. 2617

ALTERNATIVE ORDER

AND NOW, this day of 2023, upon consideration of the Preliminary Objections of Defendants The Pennsylvania Hospital of the University of Pennsylvania Health System d/b/a Pennsylvania Hospital and The Trustees of the University of Pennsylvania d/b/a Penn Medicine to Plaintiffs' Amended Complaint, and any Response thereto, it is hereby **ORDERED** that the Preliminary Objections are **SUSTAINED**. It is further **ORDERED** that:

1. Count VI of Plaintiffs' Complaint is **DISMISSED** with prejudice;
2. Count VII of Plaintiffs' Complaint is **DISMISSED** with prejudice;
3. Plaintiffs' claims for punitive damages as to Defendants The Pennsylvania Hospital of the University of Pennsylvania Health System d/b/a Pennsylvania Hospital and The Trustees of the University of Pennsylvania d/b/a Penn Medicine are **DISMISSED** with prejudice, along with all allegations of oppressive, reckless, malicious, outrageous, intentional and/or fraudulent conduct;
4. Plaintiff Holli Carter's claims in her own right are **DISMISSED** with prejudice;
and
5. Plaintiffs' Complaint is **STRICKEN** for lack of an appropriate verification.

BY THE COURT:

J.

BURNS WHITE LLC
By: James A. Young, Esq.
Richard S. Margulies, Esq.
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Attorneys For Defendants,
The Pennsylvania Hospital of the University of
Pennsylvania Health System d/b/a Pennsylvania
Hospital and The Trustees of the University of
Pennsylvania d/b/a Penn Medicine

Alice Stills, on her own behalf and as Parent and
Natural Guardian of M.E., a minor

Plaintiffs

v.

MEAD JOHNSON & COMPANY, LLC, et al.

Defendants.

COURT OF COMMON PLEAS
PHILADELPHIA COUNTY

CIVIL DIVISION

MARCH TERM, 2022
NO. 2617

**PRELIMINARY OBJECTIONS OF DEFENDANTS THE PENNSYLVANIA HOSPITAL
OF THE UNIVERSITY OF PENNSYLVANIA HEALTH SYSTEM AND THE
TRUSTEES OF THE UNIVERSITY OF PENNSYLVANIA
TO PLAINTIFFS' AMENDED COMPLAINT**

Defendants The Pennsylvania Hospital of the University of Pennsylvania Health System (“Pennsylvania Hospital”) and the Trustees of the University of Pennsylvania (hereinafter “Moving Defendants”) hereby preliminarily object to Plaintiffs’ Amended Complaint, and, in support thereof, aver as follows:

I. INTRODUCTION

1. Plaintiffs instituted this action via the filing of a Complaint on March 24, 2022 against Moving Defendants as well as Co-Defendants Mead Johnson & Company, LLC, Mead Johnson Nutritional Company (collectively referred to as “Mead Johnson”) and Abbott

Laboratories (“Abbott”). See Plaintiffs’ Complaint, attached as Exhibit “A.”¹ On September 8, 2023, Plaintiffs filed an Amended Complaint. See Plaintiffs’ Amended Complaint, attached as Exhibit “B.”

2. Plaintiffs have filed a slew of essentially identical lawsuits against Pennsylvania Hospital and other hospitals in Philadelphia based on claims relating to alleged ingestion of cow’s milk-based infant formula by premature infants following their birth.²

3. Plaintiffs allege that “upon information and belief” the Plaintiff-minors, including M.E., were diagnosed with necrotizing enterocolitis (NEC), a gastrointestinal disorder that premature infants are at increased risk to develop. See Plaintiffs’ Amended Complaint, attached as Exhibit “B,” ¶ 13. Plaintiffs allege that premature infants fed with their mother’s breast milk or donor breast milk are at decreased risk of developing NEC as compared with infants given cow’s milk-based infant formula.³

4. In addition to asserting product liability claims against the infant formula manufacturers Mead Johnson and Abbott, Plaintiffs have alleged that Moving Defendants are liable based on theories of failure to warn and corporate liability.⁴

¹ Shortly after the filing of the Complaint, this case was removed to federal court. Following briefing and a hearing, the case was remanded to this Honorable Court. There was then an effort by all Defendants to transfer these cases to this Court’s Mass Tort Program. Plaintiffs opposed this request, and same was denied by this Honorable Court. These preliminary objections were timely filed after the initial filing of the Complaint, but never ruled upon.

² Lawsuits involving identical claims have been filed against the Hospital of the University of Pennsylvania, Temple University Hospital, Albert Einstein Medical Center and Thomas Jefferson University Hospital.

³ Although Plaintiffs aver in the Amended Complaint that NEC is caused by cow’s milk-based infant formula, as discussed *infra* and in the accompanying Memorandum of Law, Plaintiffs do not cite any study or statement in the Amended Complaint that indicates NEC is caused by cow’s milk-based infant formula.

⁴ As is discussed in detail in the accompanying Memorandum of Law, infant formulas are regulated by the United States Food and Drug Administration and require to include specified vitamins and nutrients, including infant formulas intended for low birth weight infants. The FDA permits does not restrict the use of cow’s milk-based infant formula for premature or low birth weight infants. Plaintiffs’ contention that cow’s milk-based infant formula should never be given to premature infants is not supported by the FDA.

5. The factual background regarding the Plaintiff-minor's birth, diagnosis and injuries are limited to four paragraphs in the Amended Complaint.

6. Plaintiffs aver that M.E. was born prematurely on September 28, 2007 and that "upon information and belief was fed Similac and/or Enfamil cow's milk-based products by staff at Pennsylvania Hospital from shortly after his birth." *Id.*, ¶¶ 11-12.

7. Plaintiffs further allege that "upon information and belief" M.E. developed NEC shortly after first ingesting the Defendant manufacturers' products. *Id.*, ¶ 13.

8. Plaintiffs generally allege that M.E. "suffered injuries, including but not limited to a diagnosis of NEC, treatment with antibiotics and surgery, feeding difficulties, neurological injuries, developmental delays, and growth issues and he continues to suffer other long-term health effects." *Id.*, ¶ 14.

9. Moving Defendants Preliminarily Object to Plaintiffs' Amended Complaint for the reasons stated below and as more fully set forth in the accompanying Memorandum of Law, which is incorporated herein by reference.

II. ARGUMENT

A. DEMURRER TO COUNT VI: FAILURE TO WARN

10. Plaintiffs allege in Count VI of the Amended Complaint that Moving Defendants, "as purchaser, supplier, and/or distributor of the products at issue in the litigation" owed Plaintiffs and the public a duty to provide products that were free of unreasonable risk of harm.

11. Plaintiffs' theory against Moving Defendants is that they were aware cow's milk-based products made by the Defendant Manufacturers cause NEC in premature and low birth weight infants and negligently failed to warn the parents of those infants of this danger.

12. In support of this theory, Plaintiffs simply aver that “(e)xtensive scientific research, including numerous randomized controlled trials, has confirmed that cow’s milk-based feeding products cause NEC in preterm and low-birth-weight infants, which may in turn lead to other medical complications, surgeries, long-term health problems, and death.” *See* Exhibit “B,” ¶16.

13. Taking these facts as pleaded by Plaintiffs as true, Plaintiffs have failed to state a claim for negligent failure to warn against Moving Defendants as they have failed to demonstrate the product in question is indeed unreasonably dangerous.

14. Further, to the extent the product at issue was provided in the context of medical care, rather than commerce, there can be no claim against Moving Defendants for a product-liability based theory of failure to warn.

15. “Pennsylvania has adopted the Restatement (Second) of Torts in cases involving a claim of negligent failure to warn.” *Dauphin Deposit Bank & Trust Co. v. Toyota Motor Corp.*, 596 A.2d 845, 850 (Pa. Super. 1991). Section 388 governs this cause of action, and provides:

One who supplies directly or through a third person a chattel for another to use is subject to liability to those whom the supplier should expect to use the chattel with the consent of the other or to be endangered by its probable use, for physical harm caused by the use of the chattel in the manner for which and by a person for whose use it is supplied, if the supplier

- (a) knows or has reason to know that the chattel is or is likely to be dangerous for the use for which it is supplied, and
- (b) has no reason to believe that those for whose use the chattel is supplied will realize its dangerous condition, and
- (c) fails to exercise reasonable care to inform them of its dangerous condition or of the facts which make it likely to be dangerous.

Restatement (Second) of Torts § 388.

16. “The threshold inquiry in all products liability cases is whether there is a defect which rendered the product unreasonably dangerous.” *Weiner v. American Honda Motor Co., Inc.*, 718 A.2d 305, 307 (Pa. Super. 1998).

17. “A product is defective when it is not safe for its intended use, i.e., the product left the supplier's control lacking any element necessary to make it safe for its intended use.” *Id.* At 308.

18. Based on the foregoing, Plaintiffs must aver sufficient facts demonstrating the Defendant Manufacturers’ products are unreasonably dangerous for their intended use, triggering Moving Defendants’ duty to warn.

19. Although Plaintiffs vaguely refer in their Amended Complaint to research studies and trials relating to the purported risks of cow’s milk-based products in premature infants, no such studies have been cited for the proposition that feeding premature infants cow’s milk-based formula causes NEC in preterm and low-birth-weight infants.

20. At the outset, Plaintiffs appropriately acknowledge that “[p]reterm and low-birth-weight infants are *especially susceptible to NEC*.” See Exhibit “B” at ¶ 16 (emphasis added). Following this, Plaintiffs make the core claim of their Amended Complaint – that cow’s milk-based feeding products cause NEC in preterm and low birth weight infants – and that “[e]xtensive scientific research, including numerous randomized controlled trials” confirm this claim. *Id.* However, Plaintiffs fail to cite any such research or trials with specificity to support their claim.

21. Simply put, Plaintiffs have failed to state a claim for negligent failure to warn against Moving Defendants as they have failed to state facts to establish that cow’s milk-based infant formula is unreasonably dangerous for its intended purpose.

22. Further, assuming *arguendo* that the Defendant Manufacturers' cow's milk-based feeding products can be seen as unreasonably dangerous for their intended use as opposed to simply being a less effective alternative to breast milk products, Moving Defendants still had no duty to warn of the nature of cow's milk-based products under § 388 because medical providers are not "supplying" a product to a patient within the stream of commerce.

23. Plaintiffs' failure to warn claim is similarly precluded to the extent that Plaintiffs are alleging that Defendants, in providing medical care to Plaintiff-minor, failed to obtain Plaintiff-parent's consent to the use of cow's milk-based products and failed to warn of the purported risks and alternatives of such products.

24. The sole basis upon which Plaintiffs can proceed against Moving Defendants for "failure to warn" in the context of providing medical care is to assert such a claim under a theory of failure to obtain informed consent.

25. Claims for informed consent in medical malpractice actions are governed by the Medical Care Availability and Reduction of Error Act, which provides as follows:

(a) **Duty of Physicians.**--Except in emergencies, a physician owes a duty to a patient to obtain the informed consent of the patient or the patient's authorized representative prior to conducting the following procedures:

- (1) Performing surgery, including the related administration of anesthesia.
- (2) Administering radiation or chemotherapy.
- (3) Administering a blood transfusion.
- (4) Inserting a surgical device or appliance.
- (5) Administering an experimental medication, using an experimental device or using an approved medication or device in an experimental manner.

(b) Description of procedure.--Consent is informed if the patient has been given a description of a procedure set forth in subsection (a) and the risks and alternatives that a reasonably prudent patient would require to make an informed decision as to that procedure. The physician shall be entitled to present evidence of the description of that procedure and those risks and alternatives that a physician acting in accordance with accepted standards of medical practice would provide.

40 P.S. §1303.504 (emphasis added).

26. Since the use of infant formula in feeding premature infants is not a “procedure,” there is no basis for Plaintiffs to contend that Plaintiff-parent’s consent was required for the use of infant formula to feed her infant, including warning her of the risks or alternatives of same.

27. Further, the informed consent statute only applies to physicians, not hospitals, in the context of medical procedures. *See Morgan v. MacPhail*, 550 Pa. 202, 205 (1997).

28. Thus, a hospital cannot be held liable for a physician’s failure to obtain proper informed consent. *Valles v. Albert Einstein Medical Center*, 805 A.2d 1232 (2002).

B. DEMURRER TO COUNT VII: CORPORATE LIABILITY OF HEALTH CARE PROVIDER

29. In *Thompson v. Nason Hospital*, 591 A.2d 703, 708 (Pa. 1991), the Pennsylvania Supreme Court recognized the doctrine of corporate liability, holding that a hospital may be found directly liable for negligence if it fails to meet *any* of the following four duties: (1) a duty to use reasonable care in the maintenance of safe and adequate facilities and equipment; (2) a duty to select and retain only competent physicians; (3) a duty to oversee all persons who practice medicine within its walls as to patient care; and (4) a duty to formulate, adopt and enforce adequate rules and policies to ensure quality care for patients.

30. Plaintiffs’ corporate liability claim fails based on the same rationale as the claim for failure to warn, since both claims are based on the alleged failure to provide warnings to patients related to the use of cow’s milk-based infant formula.

31. Infant formula is regulated by the FDA, and there is no legal restriction on the use of cow's milk-based products for feeding of premature infants.

32. Indeed, the Infant Formula Act expressly acknowledges that it is permissible to provide cow's-milk based products to low birth weight infants.

33. Further, as discussed above, Plaintiffs cannot demonstrate that cow's milk-based formula is an unreasonably dangerous product.

34. Thus, there is no legal basis to contend that Moving Defendants can be held liable pursuant to a theory of corporate liability for failing to prevent the use of cow's milk-based products in the feeding of premature infants in the hospital.

35. Additionally, Courts considering the application of the duties set forth in *Thompson* have insisted on more than a simple finding of a negligent act by someone for whom the hospital is purportedly responsible. *Edwards v. Brandywine Hospital*, 652 A.2d 1382 (Pa. Super. 1995).

36. In considering whether the plaintiff could sustain corporate negligence claims based on these allegations, the *Edwards* court analyzed the Thompson decision and delineated the standards required to sustain such a claim:

The *Thompson* theory of corporate liability **will not be triggered every time something goes wrong in a hospital which harms a patient . . .** To establish corporate negligence, a plaintiff must show more than an act of negligence by an individual for whom the hospital is responsible. Rather, Thompson requires a plaintiff to show that the hospital itself is breaching a duty and is somehow substandard...*Thompson* contemplates a kind of '**systemic negligence**'...

Id. at 1386-87 (citations omitted and emphasis added).

37. Thus, a hospital may not be held liable via corporate negligence simply based on the alleged negligence of an individual health care provider.

38. Accordingly, even if Plaintiffs could establish that the use of cow's milk-based infant formula was a breach of the standard of care by unidentified health care providers based on the

specific circumstances of the Plaintiff-minor's case herein, which has not been pleaded by Plaintiffs considering the paucity of the allegations in the Amended Complaint, such evidence cannot support a finding of corporate liability.

39. Additionally, even assuming Plaintiffs had a viable corporate negligence claim against Pennsylvania Hospital, any such claim is precluded against the Trustees of the University of Pennsylvania since it is not a hospital.

40. The *Thompson* holding has been extended to HMO's and nursing home facilities, where it was determined that such entities performed similar functions as hospitals. *See Shannon v. Health America Pennsylvania, Inc.*, 718 A.2d 828 (Pa. Super. 1998); *Scampone v. Highland Park Care Center, LLC*, 57 A.3d 582 (Pa. 2012).

41. However, courts have routinely refused to extend the *Thompson* holding past such institutions to cover other entities, such as medical clinics and physician practice groups. *See Sutherland v. Monongahela Valley Hospital*, 856 A.2d 55, 62 (Pa. Super. 2004); *Dowhouer v. Judson*, 45 Pa. D. & C.4th 172, 180 (Pa.Com.Pl. 2000); *Brewer v. Geisinger Clinic, Inc.*, 45 Pa. D. & C.4th 215, 223 (Pa.Com.Pl. 2000); *Dibble v. Penn State Geisinger Clinic, Inc.*, 42 Pa. D. & C.4th 225 (Pa.Com.Pl. 1999); *Davis v. Gish*, 5 Pa. D. & C.5th 154, 159 (Pa.Com.Pl. 2007).

42. There is no legal basis for holding that the purported corporate parent of a hospital, such as the Trustees of the University of Pennsylvania, can be held liable under a theory of corporate negligence.

43. Indeed, the *Scampone* Court cautioned that the trial court should ensure that "multiple entities are not exposed to liability for breach of the same non-delegable duties." 57 A.2d at 606-07.

C. MOTION TO STRIKE PLAINTIFFS' COMPLAINT FOR INSUFFICIENT SPECIFICITY AS TO THE FACTS AND ALLEGED INJURIES

44. Pursuant to Pa.R.C.P. 1028(a)(3), a party may file preliminary objections in the nature of a motion to strike for insufficient specificity in a pleading.

45. A plaintiff's Complaint is required to provide a defendant with notice of what the plaintiff's claims are and the grounds upon which they rest, and the complaint must also formulate the issues by summarizing the facts essential to support the claims. *Alpha Tau Omega Fraternity v. The University of Pennsylvania*, 464 A.2d 1349, 1352 (Pa. Super. 1983) (*citations omitted*).

46. Pennsylvania Rule of Civil Procedure 1019(a) provides that "the material facts on which a cause of action or defense is based shall be stated in a concise and summary form." Pa.R.C.P. 1019(a). As the Superior Court has noted,

Rule 1019(a) requires fact pleading. The purpose of 1019(a) is to require the pleader to disclose the material facts sufficient to enable the adverse party to prepare his case. **A complaint therefore must do more than give the defendant fair notice of what the plaintiff's claim is and the grounds upon which it rests. It should formulate the issues by fully summarizing the material facts. Material facts are ultimate facts, i.e., those facts essential to support the claim. Evidence from which such facts may be inferred not only need not but should not be alleged. Allegations will withstand challenge under 1019(a) if (1) they contain averments of all of the facts a plaintiff will eventually have to prove in order to recover, and (2) they are sufficiently specific so as to enable defendant to prepare his defense.**

Baker v. Rangos, 324 A.2d 498, 505-506 (Pa. Super. 1974) (*citations and internal quotations omitted*)(emphasis added).

47. Further, it is well established that, with regard to the description of injuries sustained by a plaintiff, the Complaint must be stated with sufficient particularity to put the defendant on notice of evidence that may be produced at trial. *Kelly v. Martino*, 99 A.2d 901 (Pa. 1953). **A plaintiff's Complaint must set forth the extent, nature, location and duration of the injuries suffered, and injuries that are permanent should be stated specifically.** *Miller v.*

Perrige, 71 Pa. D. & C.2d 476, 479–80 (Pa. Com. Pl. 1975). *See, also, Kopan v. Hawk*, 14 Pa. D. & C.2d 713, 714 (Pa. Com. Pl. 1958) (“A catchall averment of “other injuries” is nothing more than a generalized averment under which any injuries whatever could be proved at the trial. Defendant would have no knowledge in advance of the trial of what they are.”)

48. Plaintiffs’ Complaint is woefully deficient with regard to the specificity of the allegations of the relevant facts and injuries at issue in this case.

49. Plaintiffs’ description of the material facts relating to the minor’s care and treatment, diagnosis and injuries is limited to four paragraphs, which are utterly insufficient to enable defendants to prepare their defenses. *See* Exhibit “B,” ¶¶ 11-14.

50. Plaintiffs aver that the minor was born prematurely, the gestational age, and birth weight; however, Plaintiffs’ allegation that “upon information and belief,” the minor was fed Similac and/or Enfamil shortly after his birth (*Id.* at ¶ 12) does not comply with the fact-pleading requirements of Rule 1019(a), since such allegations do not provide defendants with appropriate notice of the facts as to whether the minor actually ingested cow’s milk-based products.

51. Further, Plaintiffs have failed to identify which of the numerous products sold by Abbott and Mead Johnson under the Similac and Enfamil brand names were ingested by the minor.

52. Plaintiffs’ Amended Complaint further fails to provide a description of the material facts as to the period of time in which such products were ingested, when the minor was allegedly diagnosed with NEC and what treatment was provided for that condition.

53. The Amended Complaint further fails to state the nature of the injuries and “long-term health effects” that are alleged to have resulted from the diagnosis of NEC with specificity.

54. Plaintiffs' damages claim is not stated with particularity, is amorphous, vague, and open-ended. Pursuant to Pennsylvania pleading requirements, Moving Defendants should not be compelled to defend a claim for which the statement of injury is unspecified and subject to change.

55. These omissions are fatal defects in Plaintiffs' Amended Complaint. Therefore, Plaintiffs' Amended Complaint should be stricken in its entirety.

D. MOTION TO STRIKE PLAINTIFFS' CLAIMS FOR PUNITIVE DAMAGES

56. In the *Ad Damnum* clauses of Counts VI and VII of the Amended Complaint, Plaintiffs make baseless accusations that Moving Defendants engaged in oppressive, reckless, malicious and/or fraudulent conduct that allegedly justify an award of punitive damages.

57. However, the Complaint contains no specific allegations of conduct that would permit recovery of punitive damages as to Moving Defendants.

58. Rather, Plaintiffs merely allege vaguely that Moving Defendants "negligently, outrageously, and recklessly supplied and distributed the Defendant Manufacturers' milk-based infant feeding products to these healthcare professionals and medical staff for use on premature infants, including the Injured Infant," *See* Exhibit "B" at ¶135, absent any context to indicate that such an action was inappropriate based on the specific issues involved in M.E.'s medical care and condition following birth.

59. For example, the Amended Complaint gives no indication of whether Plaintiff-parent refused or was unable to provide breast milk and provides no information as to discussions between her and any health care providers regarding the purported use of cow's milk-based products.

60. Plaintiffs' allegations of oppressive, malicious and similar conduct must be rejected as mere boilerplate. As discussed above, the FDA specifically approves the use of infant formula

in care of low birth weight infants, with no restriction as to the use of cow's milk-based products for such infants.

61. Indeed, the fact that Plaintiffs have filed numerous lawsuits against at least five hospitals in Philadelphia based on identical claims belies the contention that Moving Defendants engaged in outrageous or malicious conduct in allegedly feeding the Plaintiff-minor with cow's milk-based infant formula.

62. Absent specific factual allegations to justify the claim that the use of infant formula in M.E.'s case was extreme and outrageous, there is no basis for an award of punitive damages in this case.

63. Merely contending that punitive damages should be awarded with no supporting factual justification requires dismissal of the claim.

64. Since the purpose of punitive damages is not compensation of a plaintiff but punishment of the defendant and deterrence, punitive damages can be awarded only for conduct involving some element of outrage. *Hutchinson v. Luddy*, 582 Pa. 114, 870 A.2d 766 (2005). For that reason, Pennsylvania Supreme Court decisions establish that "punitive damages are an 'extreme remedy' available in only the most exceptional matters." *Wagner v. Onofrey*, 2006 Pa. Dist. & Cnty. Dec. LEXIS 333, *11 (Pa. Com. Pl. 2006) (citing *Phillips v. Cricket Lighters*, 584 Pa. 179, 188, 883 A.2d 439, 445 (2005)). "In fact, punitive damages are specifically designed to heap an additional punishment on a defendant who is found to have acted in a fashion which is particularly egregious." *Wagner* at *12.

65. Punitive damages may not be awarded for misconduct that constitutes ordinary negligence such as inadvertence, mistake and errors of judgment. *Martin v. Johns-Manville Corp.*, 494 A.2d 1088, 1097 (Pa. 1985); *McDaniel v. Merck, Sharp & Dohme*, 533 A.2d 436, 437 (Pa.

Super. 1987). An award of punitive damages must be supported by evidence of conduct more serious than the mere commission of the underlying tort. *Allstate Ins. Co. v. A.M. Pugh Assoc., Inc.*, 604 F. Supp. 85, 99 (M.D. Pa. 1984).

66. Specifically, with regard to punitive damages in the context of claims against health care providers, the Medical Care and Reduction of Error (MCARE) Act permits punitive damages only to be awarded as follows:

(a) Award. -- Punitive damages may be awarded for conduct that is the result of the health care provider's willful or wanton conduct or reckless indifference to the rights of others. In assessing punitive damages, the trier of fact can properly consider the character of the health care provider's act, the nature and extent of the harm to the patient that the health care provider caused or intended to cause and the wealth of the health care provider.

(b) Gross Negligence. -- A showing of gross negligence is insufficient to support an award of punitive damages.

40 P.S. §1303.505.

67. The Supreme Court has made clear that when assessing the propriety of the imposition of punitive damages, "the state of mind of the actor is vital. The act or failure to act, must be intentional, reckless or malicious." *Hutchinson, supra* at 770. An appreciation of the risk is a necessary element of the mental state required for the imposition of punitive damages. *Id.* at 772.

68. Thus, "a punitive damages claim must be supported by evidence sufficient to establish that (1) a defendant had a subjective appreciation of the risk of harm to which the plaintiff was exposed and that (2) he acted, or failed to act, as the case may be, in conscious disregard of that risk." *Id.*

69. Since professional negligence actions involve allegations that health care professionals deviated from the governing standard of care, punitive damages are generally not

recoverable in malpractice actions unless the medical provider's deviation from the applicable standard of care is so egregious as to evince a conscious or reckless disregard of a patent risk of harm to the patient. *Wagner, supra*.

70. Where the facts as averred show nothing more than negligence, a lapse in judgment, or mere inadvertence, courts in Pennsylvania have dismissed pleas and claims for punitive damages, often at the pleadings stage of litigation and even if the complaint alleged severe injuries or death. *See, e.g., Brownawell v. Bryan*, 40 Pa. D. & C.3d 604, 606 (Pa. Com. Pl. 1985) (dismissing punitive damages claim where a plaintiff alleged that a physician negligently performed a spinal fusion surgery that left the plaintiff with severe neurological defects, and noting that “**the mere pleading of outrageous conduct** does not, of course, satisfy the requirement stating facts which, if proven, would form a basis for a jury concluding that the conduct was such that an award of punitive damages was warranted.”) (emphasis added); *Wagner, supra* at *11 (contentions that physician failed to prescribe antibiotics, order certain tests or request an infectious disease consult constituted “nothing more than ordinary negligence and are insufficient to support an award of punitive damages.”); *McCardle v. Aldinger*, 5 Pa. D. & C.4th 421, 428 (Pa. Com. Pl. 1996) (sustaining preliminary objections and dismissing claim for punitive damages where the plaintiff alleged negligence in the prenatal care of her child that led to the child was stillborn and holding that “[i]t is not the outcome of the alleged negligence that is of consideration, but rather the alleged conduct of defendants that is at issue.”); *Flurer v. Pocono Medical Ctr.*, 15 Pa. D. & C.4th 645, 670 (Pa. Com. Pl. 1992) (sustaining preliminary objections and finding that plaintiffs were not “capable of pleading the requisite behavior” for an award of punitive damages where a hospital allegedly failed to properly utilize a fetal monitor on a pregnant woman who was involved in a serious car accident and thereafter delivered a stillborn child).

71. Conversely, punitive damages have been reserved for those situations that are truly egregious and utterly outrageous, and typically involve aggravating or other factors that evince a particularly reckless mind or evil motive. *See, e.g., Medvecz v. Choi*, 569 F.2d 1221, 1227-30 (3rd Cir. 1987) (anesthesiologist who abandoned patient on operating room table and left room for a lunch break without securing a suitable replacement could be liable for punitive damages to patient who suffered irreversible paralysis from anesthesia complication that developed during his absence); *Hoffman v. Memorial Osteopathic Hospital*, 492 A.2d 1382, 386-87 (Pa. Super. 1985) (evidence that emergency room physician allowed Guillain-Barre Syndrome patient suffering from neurological paralysis to remain crying and immobile on floor for two hours as physician repeatedly stepped over patient was sufficient to support punitive damages claim); *Guernsey v. County Living Personal Care Home, Inc.*, 2006 U.S. Dist. LEXIS 31450, 2006 WL 1412765 (M.D. Pa. 2006) (punitive damages recoverable from nursing home officials who allowed resident to have access to room of 86-year old Alzheimer's patient where he repeatedly raped her, since nursing home was aware of resident's prior criminal convictions for sex registration as a sexual offender under Megan's Law, and his prior instances of grabbing and kissing staff); *Lawrence v. Kunkle*, 75 D. & C. 4th 370 (Pa. Com. Pl. 2005) (patient could maintain punitive damages claim against physician who refused to perform emergency surgery because patient did not have medical insurance even though physician knew that patient would likely suffer permanent neurologic and functional deficits if surgery was delayed).

72. The facts underlying Plaintiffs' bare assertions of reckless, outrageous or similar behavior do not even remotely meet the requisite standard under Pennsylvania law that would permit an award of punitive damages.

73. Additionally, pursuant to § 505(c) of the MCARE Act, punitive damages are specifically restricted in claims involving vicarious liability:

(c) Vicarious liability. -- Punitive damages shall not be awarded against a healthcare provider who is only vicariously liable for the actions of its agent that caused the injury unless it can be shown by a preponderance of the evidence that the party knew of and allowed the conduct of its agent that resulted in an award of punitive damages.

40 P.S. §1303.505(c).

74. Plaintiffs allege in this action that unidentified “staff” fed M.E. Similac and/or Enfamil at Pennsylvania Hospital shortly after his birth and failed to warn Plaintiff-parent of the alleged risks of such products. See Exhibit “B,” ¶ 12.

75. Even if such actions were claimed to be egregious or malicious such that punitive damages were permissible, which is denied for the reasons stated above, Plaintiffs must allege facts to establish that Moving Defendants had actual knowledge of the alleged wrongful conduct and nevertheless allowed it. *See Zazzera v. Roche*, 54 D. & C. 4th 225, 238 (Pa. Com. Pl. 2001); *Dean Witter Reynolds, Inc. v. Genteel*, 499 A.2d 637 (Pa. Super. 1985).

76. In this matter, Plaintiffs have failed to plead any facts to suggest that Moving Defendants were aware of any alleged misconduct by any individual alleged to be an agent and allowed such conduct to continue.

77. For all these reasons, Plaintiffs’ demand for punitive damages must be stricken with prejudice as to Moving Defendants, along with all allegations of reckless and similar conduct.

E. MOTION TO DISMISS PLAINTIFF-PARENT’S CLAIMS

78. Plaintiff-parent seeks to recover damages in her own right and as the parent and natural guardian of M.E.

79. Plaintiffs' Amended Complaint includes allegations in each count asserted as to Moving Defendants in which it is averred that Plaintiff-parent "suffered significant emotional distress, loss of income, and/or other harms. Her life has been significantly altered by the Injured Infant's injuries." *See* Exhibit "B," ¶¶ 142, and 163.

80. However, no specific cause of action is asserted as to any damages sought on behalf of Plaintiff-parent, who is not alleged in the Amended Complaint to have suffered any physical injuries as a result of the alleged negligent conduct of Moving Defendants. For this reason, Plaintiff-parent's claim should be dismissed.

81. Further, even if Plaintiff-parent had properly articulated a cause of action in the Complaint to allow her to recover damages in her own right, the Complaint should be stricken pursuant to Pa.R.C.P. 1020(b), which provides as follows:

If persons join as plaintiffs under Rules 2228, 2229(a) or (e), the complaint shall state the cause of action, any special damage, and the demand for relief of each plaintiff in a separate count, preceded by a heading naming the parties to the causes of action therein set forth.

82. Accordingly, it is improper for Plaintiffs to plead in a single count claims on behalf of both the Plaintiff-minor and the Plaintiff-parent, as was done in the Amended Complaint filed herein. Claims on behalf of each of the Plaintiffs must be set forth in separate counts of the Complaint, specifically identifying the cause of action asserted and relief sought in each count.

83. Additionally, although the statute of limitations for claims asserted on behalf of minors are tolled until the age of majority, Plaintiff-parent's claims were not similarly tolled and were required to have been brought within two years of the alleged injury. *See Hathi v. Krewstown Park Apts*, 561 A.2d 1261 (Pa. Super. 1989); 42 Pa.C.S. § 5524.

84. Plaintiffs allege that M.E. was born on September 28, 2007, was fed the Defendant manufacturers' products shortly after his birth, and developed NEC shortly thereafter. *See* Exhibit "B," ¶¶ 11-13.

85. Thus, since the Complaint herein was filed on March 24, 2022, Plaintiff-parent's claims herein are clearly time-barred based on the applicable statute of limitations.

86. In an attempt to circumvent the statute of limitations issues for the Plaintiff-parent, Plaintiffs go to great lengths in their Amended Complaint to essentially assert that Plaintiff-parent's claims are somehow preserved by way of the discovery rule. *See*, Exhibit "B" ¶¶ 23 – 41.

87. However, it is well established in Pennsylvania that a plaintiff need not know the precise extent of injuries before the statutory period begins to run. *Levenson v. Souser*, 384 Pa. Super. 132, 557 A.2d 1081, 1090 (1989).

88. Furthermore, any contention by Plaintiffs that the statute of limitations must be tolled until such time that a plaintiff first suspected that there had been medical negligence with regard to her infant's treatment must similarly be rejected.

89. It is well settled law that, in accordance with the discovery rule, a plaintiff need not know that she has a cause of action or suspects there has been negligence before the statute of limitations commences. *Colonna v. Rice*, 664 A.2d 979, 981 (Pa. Super. 1995); *Bigansky v. Thomas Jefferson Univ. Hosp.*, 658 A.2d 423, 427, 431 n.5 (Pa. Super. 1995); *Brooks v. Sagovia*, 636 A.2d 1201, 1204 (Pa. Super. 1994); *E.J.M. v. Archdiocese of Phila.*, 622 A.2d 1388, 1394 (Pa. Super. 1993); *DeMartino v. Albert Einstein Med. Center*, 460 A.2d 295, 298-299 (Pa. Super. 1983).

90. Indeed, it has been expressly held that "[k]nowledge of the negligence is not part of the discovery rule." *DeMartino, supra*, 460 A.2d at 299.

91. A plaintiff need only know that there was an injury and who caused that injury, a plaintiff need not know the full extent of the injury or even suspect negligence. *Nicolaou v. Martin*, 195 A.3d 880, 892-93 (Pa. 2018); *Gleason v. Borough of Moosic*, 15 A.3d 479, 484 (Pa. 2011); *Wilson v. El-Daief*, 964 A.2d 354, 364 (Pa. 2009).

92. Based upon the facts plead by Plaintiffs, M.E. is alleged to have developed NEC shortly after his birth. See Exhibit “B” ¶¶11 – 14. Accordingly, Plaintiff-parent knew of an injury in 2007, making any claim in her own right clearly time barred, regardless of whether she knew the extent of any claimed injury and/or when she suspected that the injury was caused by negligence.

F. MOTION TO STRIKE PLAINTIFFS’ COMPLAINT FOR FAILURE TO COMPLY WITH Pa.R.C.P. 1024

93. Pennsylvania Rule of Civil Procedure 1024(a) requires verification of every pleading containing a factual averment based upon the signer’s personal knowledge or information and belief.

94. Rule 1024(c) requires that the verification be made by one or more of the parties filing the pleading.

95. In this case, no verification is attached to the Amended Complaint in violation of Rule 1024. *See* Exhibit “B.”

96. Accordingly, the Amended Complaint should be stricken for lack of an appropriate verification.

WHEREFORE, Defendants The Pennsylvania Hospital of the University of Pennsylvania Health System d/b/a Pennsylvania Hospital and The Trustees of the University of Pennsylvania d/b/a Penn Medicine respectfully request that this Honorable Court sustain the instant Preliminary Objections and enter the attached proposed Order.

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BY: 

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Alice Stills, on her own behalf and as Parent and Natural
Guardian of M.E., a minor

Plaintiffs

v.

MEAD JOHNSON & COMPANY, LLC, et al.

Defendants.

COURT OF COMMON PLEAS
PHILADELPHIA COUNTY

CIVIL DIVISION

MARCH TERM, 2022
NO. 2617

**MEMORANDUM OF LAW IN SUPPORT OF PRELIMINARY OBJECTIONS OF
DEFENDANTS THE PENNSYLVANIA HOSPITAL OF THE UNIVERSITY OF
PENNSYLVANIA HEALTH SYSTEM AND THE TRUSTEES OF THE UNIVERSITY
OF PENNSYLVANIA TO PLAINTIFFS' COMPLAINT**

I. MATTER BEFORE THE COURT

Preliminary Objections of Defendants The Pennsylvania Hospital of the University of Pennsylvania Health System ("Pennsylvania Hospital") and The Trustees of the University of Pennsylvania to Plaintiffs' Amended Complaint.

While patently obvious that Plaintiffs' Amended Complaint must be dismissed for clear and important violations of the procedural requirements governing pleadings and verification of the accuracy of the factual averments of the Amended Complaint (there are not separate counts identified for the causes of action of each of the Plaintiffs attempts to allege), most of which are averred "upon information and belief," the substance of Plaintiffs' allegations do not support any legally recognized cause of action against Moving Defendants, under Pennsylvania law. Our

procedural rules do not permit a plaintiff to simply identify allegedly tortious conduct by a defendant without pleading the necessary facts to satisfy the elements of the tortious conduct.

Here, Plaintiffs plead that Moving Defendants permitted Co-Defendants' cow's milk-based infant formula to be fed to prematurely born infants, which allegedly caused those infants to develop necrotizing enterocolitis ("NEC"). Plaintiffs then plead themselves out of Court by attempting to support a "failure to warn" claim by referencing unnamed studies and trials in an attempt to establish that cow's milk-based infant formulas cause NEC. Thus, distinct from the Amended Complaint's procedural shortcomings, Plaintiffs have failed to plead facts that support the "failure to warn" and corporate liability causes of action that they attempt to assert against Moving Defendants. It is further noteworthy that there is no viable "failure to warn" cause of action that is recognized under Pennsylvania law against Moving Defendants, as explained in this submission by Moving Defendants.

II. STATEMENT OF QUESTIONS PRESENTED

1. Whether this Honorable Court should dismiss Count VI of Plaintiffs' Amended Complaint "Failure to Warn" cause of action with prejudice because Plaintiffs' Amended Complaint does not support the claim that cow's milk-based products are unreasonably dangerous and Moving Defendants cannot be held liable for negligent failure to warn on the basis that they are a supplier of such products?

Suggested answer in the affirmative.

2. Whether this Honorable Court should dismiss Count VI of Plaintiffs' Amended Complaint "Failure to Warn" cause of action with prejudice because it improperly alleges that Moving Defendants were required to obtain Plaintiff-parent's informed consent to use of cow's

milk-based products for feeding of Plaintiff-minor and warn her of the risks and/or alternatives of same?

Suggested answer in the affirmative.

3. Whether this Honorable Court should dismiss Count VII of Plaintiffs' Amended Complaint "Corporate Negligence" cause of action with prejudice because Moving Defendants cannot be held liable on such a theory for a product which is regulated by the FDA and which is not precluded for use in premature or low birth weight infants, and where a hospital cannot be held liable for corporate negligence based on the alleged negligence of an individual health care provider?

Suggested answer in the affirmative.

4. Whether this Honorable Court should dismiss Count VII of Plaintiffs' Amended Complaint "Corporate Negligence" cause of action with prejudice as to the Trustees of the University of Pennsylvania since it is not a hospital and because corporate negligence duties are non-delegable?

Suggested answer in the affirmative.

5. Whether this Honorable Court should strike Plaintiffs' Amended Complaint in its entirety for insufficient specificity of the facts and alleged injuries?

Suggested answer in the affirmative.

6. Whether this Honorable Court should strike Plaintiffs' claims for punitive damages as to Moving Defendants because the Amended Complaint fails to plead facts providing a basis for an award of punitive damages?

Suggested answer in the affirmative.

7. Whether this Honorable Court should strike Plaintiff-parent's claims for failure to state a cause of action, and for failure to plead separate causes of action pursuant to Pa.R.C.P. 1020 and based on the applicable statute of limitations?

Suggested answer in the affirmative.

8. Whether this Honorable Court should strike Plaintiffs' Amended Complaint for failure to provide a client verification as required by Pa.R.C.P. 1024?

Suggested answer in the affirmative.

III. INTRODUCTION AND FACTUAL BACKGROUND

Plaintiffs have filed a slew of essentially identical lawsuits against Pennsylvania Hospital and other hospitals in Philadelphia based on claims relating to alleged ingestion of cow's milk-based products by premature infants in the hospital following their birth.¹ Plaintiffs allege that the Plaintiff-minors, including M.E., were diagnosed with necrotizing enterocolitis (NEC), a gastrointestinal disorder that premature infants are at increased risk to develop. *See* Plaintiffs' Amended Complaint, attached as Exhibit "B" at ¶ 14. Plaintiffs aver that premature infants fed with their mother's breast milk or donor breast milk are at decreased risk of developing NEC as compared with infants given cow's milk-based products (infant formula). Many of the allegations of the Complaint are pleaded "upon information and belief," including the allegations that Plaintiff-minors received infant formula and that they developed NEC shortly after being fed with infant formula.

In addition to asserting product liability claims against the infant formula manufacturers Mead Johnson & Company, LLC, Mead Johnson Nutritional Company (collectively referred to as

¹ Lawsuits involving identical claims have been filed against the Hospital of the University of Pennsylvania, Temple University Hospital, Albert Einstein Medical Center and Thomas Jefferson University Hospital.

“Mead Johnson”) and Abbott Laboratories (“Abbott”)², Plaintiffs have alleged that Moving Defendants are liable based on theories of failure to warn and corporate liability. *See* Plaintiffs’ Amended Complaint, attached as Exhibit “B” at Counts VI and VII. As is discussed in detail below, Plaintiffs’ claims against Moving Defendants are legally and factually deficient.

Although Plaintiffs baldly aver that NEC is caused by cow’s milk-based products, Plaintiffs refer in their Amended Complaint only to research studies and trials with no specificity whatsoever. As discussed in detail *supra*, even assuming the truth of the factual allegations stated in Plaintiffs’ Amended Complaint, Plaintiffs’ allegations do not support the conclusion that NEC is caused by cow’s milk-based products. As such, there is no basis to contend that cow’s milk-based products are dangerous for premature infants, such that Moving Defendants had a duty to warn Plaintiff-parents of any risks or alternatives related to infant formula.

Plaintiffs’ Complaint provides scant information regarding the factual background of this case. Plaintiffs aver that M.E. was born prematurely on September 28, 2007 and that “upon information and belief was fed Similac and/or Enfamil cow’s milk-based products by staff at Pennsylvania Hospital from shortly after his birth.” *Id.*, ¶¶ 11-12. Plaintiffs further allege that “upon information and belief” M.E. developed NEC shortly after first ingesting the Defendant manufacturers’ products. *Id.*, ¶ 13. No specific details are provided regarding the infant’s condition following birth other than that he developed NEC on an unidentified date, that he was treated with antibiotics and surgery, and suffered from feeding difficulties, unspecified neurological injuries, unspecified developmental delays and growth issues, and continues to suffer other unspecified long-term health effects. *Id.* at ¶14. No specific facts are provided by Plaintiffs as to any medical care M.E. received, for what period of time M.E. allegedly ingested cow’s milk-based products,

² Mead Johnson and Abbott have been the subject of similar lawsuits in other states, including Connecticut, Illinois and California.

and which product(s) he allegedly ingested.³ Finally, the Amended Complaint is silent as to the nature and extent of M.E.'s alleged injuries other than a vague reference to nonspecific injuries and long term health effects. *Id.* ¶ 14.

Further, the Amended Complaint does not provide any details whatsoever regarding communications between Plaintiff-parent and medical providers at Pennsylvania Hospital regarding the allegations that M.E. may have been fed with Mead Johnson and/or Abbott cow's milk-based products in the hospital. Plaintiffs do not provide any information regarding discussions between Plaintiff-parent and any health care providers at Pennsylvania Hospital related to breastfeeding and/or using cow's milk-based products in this case, including whether or not she was encouraged to breastfeed and/or was unable or declined to do so. As noted, Plaintiffs plead that Plaintiff Minor ingested formula "on information and belief" only, and similarly plead "on information and belief" that Plaintiff Minor developed NEC as a result.

Plaintiffs further fail to disclose in their Complaint that infant formula is regulated by the United States Food and Drug Administration (FDA) and that there is no restriction on the use of cow's milk-based products for premature infants. The federal Infant Formula Act of 1980 ("IFA") was enacted "to assure the safety and nutrition of infant formulas." Pub. L. No. 96-359, 94 Stat. 1190. The IFA and its implementing regulations outline the requirements that infant formula must meet, including how infant formula is made, its contents and ingredients, and the labels used on its packages. 21 U.S.C. § 350a; 21 C.F.R. §§ 106-07. The IFA provides that infant formulas may only contain "substances that are safe and suitable for use in infant formula." 21 C.F.R. § 106.40(a). Neither the IFA nor the regulations exclude cow milk as an ingredient, and many infant formulas

³ Plaintiffs aver that Abbott sells at least seven types of products directed to preterm and/or low birth weight infants, six of which use the name Similac, and that Mead Johnson sells eight types of infant formulas using the Enfamil brand name. *Id.*, ¶¶ 48, 49.

for sale include cow milk; 21 C.F.R. § 106.3 (“infant formula” is a “food for infants by reason of its *simulation* of human milk”) (emphasis added). 21 U.S.C. § 350a; 21 C.F.R. §§ 107.50. Before selling any “new infant formula,” a manufacturer must (1) register with the FDA, and (2) submit a notice to the FDA at least 90 days before marketing such formula. The notice must also state that the formula contains the required vitamins and nutrients, as demonstrated by testing. 21 U.S.C. § 350a(b). These same FDA review procedures apply when a manufacturer makes a “major change” to an existing formula. 21 U.S.C. § 350a(c)(2)(B); 21 C.F.R. § 106.3.

Further, the FDA recognizes that certain infant formulas are intended for low birth weight babies (such as infants born prematurely) or infants with unusual medical or dietary problems. Indeed, such formulas have special review requirements. 21 U.S.C. § 350a(h); 21 C.F.R. § 107.50(a). For those formulas – known as “exempt” formulas because they may be exempted from certain requirements – the required 90-day notice must include “the label and other labeling of the infant formula, a complete quantitative formulation for the infant formula, and a detailed description of the medical conditions for which the infant formula is represented.” 21 C.F.R. § 107.50(b)(3). As with other formulas, the regulations do not exclude cow milk as an ingredient for infant formulas intended for use by an infant with a low birth weight.

Thus, since Plaintiffs do not allege that the product did not meet federal requirements, there is no basis for any claim that the product is unreasonably dangerous and/or should not be given under any circumstances to premature or low birth weight infants.

IV. ARGUMENT

A. DEMURRER TO COUNT VI: FAILURE TO WARN

1. Moving Defendants Cannot Be Held Liable to Plaintiffs Based on a Theory of Failure to Warn Because the Infant Formula is Not Unreasonably Dangerous

Pursuant to Pa.R.C.P. 1028(a)(4), a party may file preliminary objections to a complaint, in the nature of a demurrer, for legal insufficiency in a pleading. A court should grant a demurrer where, accepting as true all well pled facts, a legal cause of action cannot be maintained upon those facts. Pa.R.C.P. 1028(a)(4); *See also, Willet v. Pennsylvania Med. Catastrophe Loss Fund*, 702 A.2d 850, 853 (Pa. 1997).

Plaintiffs allege in Count VI of the Amended Complaint that Moving Defendants, “as purchaser, supplier, and/or distributor of the products at issue in the litigation” owed Plaintiffs and the public a duty to provide products that were free of unreasonable risk of harm. Plaintiffs’ theory against Moving Defendants is that they were aware cow’s milk-based products manufactured by Mead Johnson and Abbott cause NEC in premature and low birth weight infants and negligently failed to warn the parents of those infants of this danger. However, Plaintiffs do not cite any study or statement in the Amended Complaint that indicates that NEC is caused by cow’s milk-based infant formula. Taking the facts as pleaded by Plaintiffs as true, Plaintiffs have failed to state a claim for negligent failure to warn against Moving Defendants as they have failed to demonstrate the products in question are indeed unreasonably dangerous. Further, to the extent the product at issue was provided in the context of medical care, rather than commerce, there can be no claim against Moving Defendants for a product-liability based theory of failure to warn.

“Pennsylvania has adopted the Restatement (Second) of Torts in cases involving a claim of negligent failure to warn.” *Dauphin Deposit Bank & Trust Co. v. Toyota Motor Corp.*, 596 A.2d 845, 850 (Pa. Super. 1991). Section 388 governs this cause of action, and provides:

One who supplies directly or through a third person a chattel for another to use is subject to liability to those whom the supplier should expect to use the chattel with the consent of the other or to be endangered by its probable use, for physical harm caused by the use of the chattel in the manner for which and by a person for whose use it is supplied, if the supplier

- (a) knows or has reason to know that the chattel is or is likely to be dangerous for the use for which it is supplied, and
- (b) has no reason to believe that those for whose use the chattel is supplied will realize its dangerous condition, and
- (c) fails to exercise reasonable care to inform them of its dangerous condition or of the facts which make it likely to be dangerous.

Restatement (Second) of Torts § 388. To survive preliminary objections, Plaintiffs must aver sufficient facts, together with the documents and exhibits attached thereto, to make out a *prima facie* case as to all elements of the cause of action. *Northern Forests II, Inc. v. Keta Realty Co.*, 130 A.3d 19, 35 (Pa. Super. 2015).

“The threshold inquiry in all products liability cases is whether there is a defect which rendered the product unreasonably dangerous.” *Weiner v. American Honda Motor Co., Inc.*, 718 A.2d 305, 307 (Pa. Super. 1998). “A product is defective when it is not safe for its intended use, i.e., the product left the supplier's control lacking any element necessary to make it safe for its intended use.” *Id.* At 308. Whether a product is “unreasonably dangerous” is a question of law. *Id.* Based on the foregoing, Plaintiffs must aver sufficient facts demonstrating the Defendant Manufacturers’ products are unreasonably dangerous for their intended use, triggering Moving Defendants’ duty to warn. They have not done so as the studies they cite in their Complaint do not

say – based on the very allegations in the Complaint - what Plaintiffs claim they do. Therefore, Moving Defendants had no corresponding duty to warn.

At the outset, Plaintiffs appropriately acknowledge that “[p]reterm and low-birth-weight infants are *especially susceptible to NEC*.” See Exhibit “B” at ¶ 16 (emphasis added). Following this, Plaintiffs make the core claim of their Complaint – that cow’s milk-based feeding products cause NEC in preterm and low birth weight infants – a claim that is unsupported by any specific studies or trials in the Amended Complaint. *Id.* Admittedly, if a product directly causes NEC in preterm and low birth weight infants, that product would certainly be dangerous. However, Plaintiffs’ Amended Complaint does nothing to support this bald allegation.

Ultimately, Plaintiffs’ claim that Defendant Manufacturers’ cow’s milk-based feeding products cause NEC and are therefore unreasonably dangerous rests upon the notion that correlation equals causation. However, Plaintiffs have not, and cannot, establish causation. Plaintiffs readily admit at paragraph 16 of the Amended Complaint that preterm and low-birth-weight infants are especially susceptible to NEC because of their underdeveloped digestive systems. All that Plaintiffs’ Amended Complaint demonstrates, as pleaded under these facts, is that breast milk may be better at reducing that already high risk of NEC in these infants than cow’s milk-based alternatives. This proposition does not make the Defendant Manufacturers’ cow’s milk-based alternatives unreasonably dangerous within the meaning of § 388 of the Restatement (Second) of Torts and, accordingly, does not trigger a duty to warn on the part of Moving Defendants.

2. Moving Defendants Are Not a “Supplier” and, Therefore, Cannot Be Held Liable for Negligent Failure to Warn

Assuming *arguendo* that the Defendant Manufacturers’ cow’s milk-based feeding products can be seen as dangerous for their intended use as opposed to simply being a less effective

alternative to breast milk products, Moving Defendants still had no duty to warn of the nature of cow's milk-based products under § 388 because they are not considered a supplier of cow's milk-based feeding products. Plaintiffs cite to no caselaw in Pennsylvania holding that a hospital is considered a supplier under § 388. Indeed, extensive research into this topic turns up no prior decisions where a Pennsylvania court has found a hospital to be a supplier in a products liability case for negligent failure to warn.

To determine a hospital may be defined as supplier of products ancillary to and following medical services within the meaning of § 388 would be to impose on the hospital a duty to warn about every conceivable object a patient may encounter in a hospital, right down to the napkins available in the hospital cafeteria. Imposing such a duty does nothing to advance the purpose of products liability law, i.e. to protect consumers from dangerous products in the stream of commerce. Moving Defendants are not in the best position to determine what products are available in the market for premature and low weight birth infants. In light of this, Plaintiffs have not sufficiently pleaded that Moving Defendants are a supplier under § 388.

For the foregoing reasons, Plaintiffs have not pleaded sufficient facts to aver the Defendant Manufacturers' products are unreasonably dangerous for their intended use and thus have not established Moving Defendants had a duty to warn. Alternatively, even if the products at issue here can be viewed as unreasonably dangerous, Plaintiffs still have failed to plead sufficient facts that Moving Defendants are a supplier of products that are ancillary to the medical services provided to Plaintiffs. Accordingly, it is respectfully requested this Court sustain Moving Defendants' Preliminary Objections to Count VI: Failure to Warn of Plaintiffs' Amended Complaint.

3. There is no Legal Basis for Plaintiffs to Present an Informed Consent Claim Regarding the Use of Cow's milk-based products

Plaintiffs' failure to warn claim is couched in language of product liability related to Moving Defendants' alleged duty "as a purchaser, supplier and/or distributor" to provide a product (cow's milk-based infant formula) that was free of unreasonable risk of harm to consumers (parents and their premature infants). This theory fails for the reasons stated above. However, to the extent that Plaintiffs are alleging that Moving Defendants, in providing medical care to Plaintiff-minor, failed to obtain Plaintiff-parent's consent to the use of cow's milk-based products and failed to warn of the purported risks and alternatives of such products, such a claim is also clearly precluded by Pennsylvania law.

Plaintiffs broadly allege that Moving Defendants failed to warn of the alleged dangers of cow's milk-based products and provide them with information necessary "to make an informed choice about whether to allow their baby to be fed the Defendant Manufacturers' products." *See* Exhibit "B" at ¶ 137. This purported failure to warn/inform allegedly led Plaintiff-minor to be fed a cow's milk-based product that Plaintiffs' contend caused and/or increased the risk of NEC. *Id.* at ¶ 141. The sole basis upon which Plaintiffs can proceed against Moving Defendants for "failure to warn" in the context of providing medical care is to assert such a claim under a theory of failure to obtain informed consent. Plaintiffs are impliedly asserting that Moving Defendants failed to obtain Plaintiff-parent's informed consent as to whether she should use cow's milk-based infant formula to feed her child as opposed to breastfeeding or using breast donor milk, based on the alleged risks of cow's milk-based products. However, such a claim is not cognizable under Pennsylvania law.

Claims for informed consent in medical malpractice actions are governed by the Medical Care Availability and Reduction of Error Act, which provides as follows:

(a) **Duty of Physicians.**--Except in emergencies, a physician owes a duty to a patient to obtain the informed consent of the patient or the patient's authorized representative prior to conducting the following procedures:

- (1) Performing surgery, including the related administration of anesthesia.
- (2) Administering radiation or chemotherapy.
- (3) Administering a blood transfusion.
- (4) Inserting a surgical device or appliance.
- (5) Administering an experimental medication, using an experimental device or using an approved medication or device in an experimental manner.

(b) Description of procedure.--Consent is informed if the patient has been given a description of a procedure set forth in subsection (a) and the risks and alternatives that a reasonably prudent patient would require to make an informed decision as to that procedure. The physician shall be entitled to present evidence of the description of that procedure and those risks and alternatives that a physician acting in accordance with accepted standards of medical practice would provide.

40 P.S. §1303.504 (emphasis added).

The clear language of the statute above reveals two significant tenets. The first is that the informed consent statute does not apply to the use of infant formula in feeding premature infants, since that is not a "procedure." Thus, there is no basis for Plaintiffs to contend that Plaintiff-parent's consent was required for the use of infant formula to feed her infant, including warning her of the risks or alternatives of same. Second, the informed consent statute only applies to physicians, not hospitals, in the context of medical procedures. *See Morgan v. MacPhail*, 550 Pa. 202, 205 (1997).

Informed consent has not been extended to any type of therapeutic treatment involving an ingestible therapeutic drug, which the court defined as "an ongoing treatment upon examination

by the treating physician, where any change of condition can be diagnosed and controlled.” *Boyer v. Smith*, 345 Pa. Super. 66, 71, 497 A.2d 646, 648 (1985). The Superior Court ruled that the informed consent doctrine is premised upon the legal theory that the performance of a medical procedure without a patient's informed consent constitutes a technical assault or battery and that merely prescribing an oral medication does not involve a touching so not battery can occur and no informed consent is needed. *Id.* at 649. The same principles clearly apply to administration of infant formula to a newborn.

Further, an informed consent claim is only applicable to a physician and not the hospital and/or other health care entities. *See* 40 P.S. § 1303.504; *see also Kelly v. Methodist Hosp.*, 664 A.2d 148 (Pa. Super. 1995) (holding that generally only the physician who performs the operation on the patient has the duty of obtaining his consent for the procedure). The Pennsylvania Supreme Court has held that informed consent involves the relationship between a physician and the patient and that the failure to obtain proper informed consent is deemed a battery, and the institution plays no role in the communications involved in obtaining the same. *See Valles v. Albert Einstein Medical Center*, 805 A.2d 1232 (2002). In *Valles*, the Court decisively ruled that:

We find that a battery which results from a lack of informed consent is not the type of action that occurs within the scope of employment. In our view, a medical facility cannot maintain control over this aspect of the physician-patient relationship. Our lower courts have recognized that the duty to obtain informed consent belongs solely to the physician. (Citations omitted). Informed consent flows from the discussions each patient has with his physician, based on the facts and circumstances each case presents. We decline to interject an element of a hospital's control into this highly individualized and dynamic relationship. We agree with the lower court that to do so would be both improvident and unworkable. Thus, we hold that as a matter of law, a medical facility lacks the control over the manner in which the physician performs his duty to obtain informed consent so as to render the facility vicariously liable.

Id., 805 A.2d at 1239 (emphasis added). The *Valles* case remains the prevailing law in Pennsylvania. Pennsylvania courts have repeatedly applied this doctrine, recognizing and

acknowledging that “[i]n a claim alleging lack of informed consent, it is the conduct of the unauthorized procedure that constitutes the tort.” *Isaac v. Jameson Mem. Hosp.*, 932 A.2d 924, 929 (Pa. Super. 2007) (citing *Moure v. Raeuchle*, 604 A.2d 1003, 1008 (Pa. Super. 1992)). Further, “[g]iven the unique nature of the doctrine and its origins as a technical battery, hospitals cannot be held vicariously liable for a physician’s failure to obtain informed consent because ‘a medical facility cannot maintain control over this aspect of the physician-patient relationship.’” *Isaac*, 932 A.2d at 930. As such, it is clear that the instant cause of action cannot be sustained against Moving Defendants as a matter of law.

B. DEMURRER TO COUNT VII: CORPORATE LIABILITY OF HEALTH CARE PROVIDER

1. Moving Defendants Cannot be Held Liable for Corporate Negligence Regarding a Food Product Which is Permitted for its Intended Use Pursuant to Federal Law

In *Thompson v. Nason Hospital*, 591 A.2d 703, 708 (Pa. 1991), the Pennsylvania Supreme Court recognized the doctrine of corporate liability, holding that a hospital may be found directly liable for negligence if it fails to meet *any* of the following four duties: (1) a duty to use reasonable care in the maintenance of safe and adequate facilities and equipment; (2) a duty to select and retain only competent physicians; (3) a duty to oversee all persons who practice medicine within its walls as to patient care; and (4) a duty to formulate, adopt and enforce adequate rules and policies to ensure quality care for patients.

Plaintiffs’ corporate liability claim fails based on the same rationale as the claim for failure to warn. Both claims are based on the alleged failure to provide warnings to patients related to the use of cow’s milk-based infant formula. As noted above, infant formula is regulated by the FDA, and there is no legal restriction on the use of cow’s milk-based products for feeding of premature infants. Indeed, the Infant Formula Act expressly acknowledges that it is permissible to provide

cow's-milk based products to low birth weight infants. Further, as discussed above, Plaintiffs cannot demonstrate that cow's milk-based formula is a dangerous product. Thus, there is no legal basis to contend that Moving Defendants can be held liable pursuant to a theory of corporate liability for failing to preclude the use of cow's milk-based products in the feeding of premature infants in the hospital.

Additionally, Courts considering the application of the duties set forth in *Thompson* have insisted on more than a simple finding of a negligent act by someone for whom the hospital is purportedly responsible. *Edwards v. Brandywine Hospital*, 652 A.2d 1382 (Pa. Super. 1995). In considering whether the plaintiff could sustain corporate negligence claims based on these allegations, the court analyzed the Thompson decision and delineated the standards required to sustain such a claim:

The *Thompson* theory of corporate liability **will not be triggered every time something goes wrong in a hospital which harms a patient . . .** To establish corporate negligence, a plaintiff must show more than an act of negligence by an individual for whom the hospital is responsible. Rather, Thompson requires a plaintiff to show that the hospital itself is breaching a duty and is somehow substandard...*Thompson* contemplates a kind of 'systemic negligence'...

Id. at 1386-87 (citations omitted and emphasis added). Thus, corporate liability requires "more than individual acts of negligence." *Id.* As noted by the court in *Edwards*, this reading of the Court's opinion in *Thompson* is the only way to logically construe its holding, as hospitals are already held vicariously liable for the negligent acts of their employees and ostensible agents, while "Thompson requires a plaintiff to show that the **hospital itself** is breaching a duty and is somehow substandard." *Id.* at 1387; *see also MacDonald v. Chestnut Hill Hosp.*, 2005 Phila. Ct. Com. Pl. LEXIS 273, 18 (Pa. C.P. 2005) (granting nonsuit to the hospital defendant where "[t]here was no evidence that protocols were routinely ignored to the detriment of patients or that the kind of systematic negligence on the part of CHH required by the *Edwards* decision was present.")

Thus, a hospital may not be held liable via corporate negligence simply based on the alleged negligence of an individual health care provider. Accordingly, even if Plaintiffs could establish that the use of cow's milk-based infant formula was a breach of the standard of care by unidentified health care providers based on the specific circumstances of the Plaintiff-minor's case herein, which has not been pleaded by Plaintiffs considering the paucity of the allegations in the Complaint, such evidence cannot support a finding of corporate liability.

For the reasons stated above, Count VII of Plaintiffs' Complaint should be dismissed with prejudice.

2. Plaintiffs Are Precluded From Pursuing Corporate Negligence Claims as to The Trustees of the University of Pennsylvania

As noted *infra*, the Pennsylvania Supreme Court set forth certain nondelegable duties of hospitals, which if violated may support a finding of corporate negligence. The *Thompson* holding has been extended to HMO's and nursing home facilities, where it was determined that such entities performed similar functions as hospitals. See *Shannon v. Health America Pennsylvania, Inc.*, 718 A.2d 828 (Pa. Super. 1998); *Scampono v. Highland Park Care Center, LLC*, 57 A.3d 582 (Pa. 2012). However, courts have routinely refused to extend the *Thompson* holding past such institutions to cover other entities, such as medical clinics and physician practice groups. See *Sutherland v. Monongahela Valley Hospital*, 856 A.2d 55, 62 (Pa. Super. 2004); *Dowhouer v. Judson*, 45 Pa. D. & C.4th 172, 180 (Pa.Com.Pl. 2000); *Brewer v. Geisinger Clinic, Inc.*, 45 Pa. D. & C.4th 215, 223 (Pa.Com.Pl. 2000); *Dibble v. Penn State Geisinger Clinic, Inc.*, 42 Pa. D. & C.4th 225 (Pa.Com.Pl. 1999); *Davis v. Gish*, 5 Pa. D. & C.5th 154, 159 (Pa.Com.Pl. 2007).

There is no legal basis for holding that the purported corporate parent of a hospital can be held liable under a theory of corporate negligence. The Trustees of the University of Pennsylvania is not a hospital and cannot be held liable under a theory of corporate liability, regardless of its

relationship with Pennsylvania Hospital. Moreover, as Pennsylvania Courts have consistently held, corporate negligence duties are “non-delegable,” i.e., only one entity can be held liable for a breach of these duties. The *Scampone* Court cautioned that the trial court should ensure that “multiple entities are not exposed to liability for breach of the same non-delegable duties.” 57 A.2d at 606-07. Thus, even if a corporate negligence claim were permissible as to Pennsylvania Hospital, which is denied for the reasons stated above, The Trustees of the University of Pennsylvania, which is not a hospital, cannot also be exposed to liability for an alleged breach of the same, non-delegable duties arising out of the same factual allegations. Accordingly, even accepting as true all well pled facts in Plaintiffs’ Complaint, the corporate negligence claims as to the non-hospital Defendant, the Trustees of the University of Pennsylvania, are legally insufficient and must therefore be dismissed.

C. MOTION TO STRIKE PLAINTIFFS’ COMPLAINT FOR INSUFFICIENT SPECIFICITY AS TO THE FACTS AND ALLEGED INJURIES

Pursuant to Pa.R.C.P. 1028(a)(3), a party may file preliminary objections in the nature of a motion to strike for insufficient specificity in a pleading. A plaintiff’s Complaint is required to provide a defendant with notice of what the plaintiff’s claims are and the grounds upon which they rest, and the complaint must also formulate the issues by summarizing the facts essential to support the claims. *Alpha Tau Omega Fraternity v. The University of Pennsylvania*, 464 A.2d 1349, 1352 (Pa. Super. 1983) (*citations omitted*). Pennsylvania Rule of Civil Procedure 1019(a) provides that “the material facts on which a cause of action or defense is based shall be stated in a concise and summary form.” Pa.R.C.P. 1019(a). As the Superior Court has noted,

Rule 1019(a) requires fact pleading. The purpose of 1019(a) is to require the pleader to disclose the material facts sufficient to enable the adverse party to prepare his case. **A complaint therefore must do more than give the defendant fair notice of what the plaintiff’s claim is and the grounds upon which it rests. It should formulate the issues by fully summarizing the material facts. Material facts**

are ultimate facts, i.e., those facts essential to support the claim. Evidence from which such facts may be inferred not only need not but should not be alleged. Allegations will withstand challenge under 1019(a) if (1) they contain averments of all of the facts a plaintiff will eventually have to prove in order to recover, and (2) they are sufficiently specific so as to enable defendant to prepare his defense.

Baker v. Rangos, 324 A.2d 498, 505-506 (Pa. Super. 1974) (citations and internal quotations omitted)(emphasis added).

Further, it is well established that, with regard to the description of injuries sustained by a plaintiff, the Complaint must be stated with sufficient particularity to put the defendant on notice of evidence that may be produced at trial. *Kelly v. Martino*, 99 A.2d 901 (Pa. 1953). **A plaintiff's Complaint must set forth the extent, nature, location and duration of the injuries suffered, and injuries that are permanent should be stated specifically.** *Miller v. Perrige*, 71 Pa. D. & C.2d 476, 479–80 (Pa. Com. Pl. 1975). *See, also, Kopan v. Hawk*, 14 Pa. D. & C.2d 713, 714 (Pa. Com. Pl. 1958) (“A catchall averment of “other injuries” is nothing more than a generalized averment under which any injuries whatever could be proved at the trial. Defendant would have no knowledge in advance of the trial of what they are.”)

Plaintiffs' Amended Complaint is woefully deficient with regard to the specificity of the allegations of the relevant facts and injuries at issue in this case. Plaintiffs' description of the material facts relating to the minor's care and treatment, diagnosis and injuries is limited to four paragraphs, which are utterly insufficient to enable Defendants to prepare their defenses. *See* Exhibit “B,” ¶¶ 11-14. Plaintiffs aver that the minor was born prematurely, the gestational age and birth weight. Plaintiffs' allegation that “upon information and belief,” the minor was fed Similac and/or Enfamil shortly after his birth (*Id.* at ¶ 12) does not comply with the fact-pleading requirements of Rule 1019(a), since such allegations do not provide Moving Defendants with appropriate notice of the facts as to whether the minor actually ingested cow's milk-based

products. Further, Plaintiffs have failed to identify which of the numerous products sold by Abbott and Mead Johnson under the Similac and Enfamil brand names were ingested by the minor. Plaintiffs' Amended Complaint further fails to provide a description of the material facts as to the period of time in which such products were ingested, when the minor was allegedly diagnosed with NEC, what specific treatment was provided for that condition, and for how long.

The Amended Complaint further fails to state the specific nature of the injuries and "long-term health effects" that are alleged to have resulted from the diagnosis of NEC. Plaintiffs' damages claim is not stated with particularity, is amorphous, vague, and open-ended. Pursuant to Pennsylvania pleading requirements, Moving Defendants should not be compelled to defend a claim for which the statement of injury is unspecified and subject to change.

In short, Plaintiffs' Amended Complaint is inconsistent with the requirements of the Pennsylvania Rules of Civil Procedure as to the necessary specificity for the description of the facts and alleged injuries sustained. The facts in the Complaint are pleaded almost entirely "on information and belief." These omissions are fatal defects in Plaintiffs' Amended Complaint. Therefore, Plaintiffs' Amended Complaint should be stricken in its entirety.

D. MOTION TO STRIKE PLAINTIFFS' CLAIMS FOR PUNITIVE DAMAGES

As in the other infant formula cases, In the *Ad Damnum* clauses of Counts VI and VII of the Amended Complaint, Plaintiffs make baseless accusations that Moving Defendants engaged in oppressive, reckless, malicious and/or fraudulent conduct that allegedly justify an award of punitive damages. However, the Amended Complaint contains no specific allegations of conduct that would permit recovery of punitive damages as to Moving Defendants. Rather, Plaintiffs merely allege that "upon information and belief" M.E. may have been given a cow's milk-based infant formula following birth, absent any context to indicate that such an action was inappropriate

based on the specific issues involved in M.E.'s medical care and condition following birth. For example, the Amended Complaint gives no indication of whether Plaintiff-parent refused or was unable to provide breast milk and provides no information as to discussions between her and any health care providers regarding the purported use of cow's milk-based products.

Plaintiffs' allegations of oppressive, malicious and similar conduct must be rejected as mere boilerplate. As discussed above, the FDA specifically approves the use of infant formula in care of low birth weight infants, with no restriction as to the use of cow's milk-based products for such infants. Indeed, the fact that Plaintiffs have filed numerous lawsuits against at least four hospitals in Philadelphia based on identical claims belies the contention that Moving Defendants engaged in outrageous or malicious conduct in allegedly feeding the Plaintiff-minor with cow's milk-based infant formula. Absent specific factual allegations to justify the claim that the use of infant formula in M.E.'s case was extreme and outrageous, there is no basis for an award of punitive damages in this case. Merely contending that punitive damages should be awarded with no supporting factual justification requires dismissal of this claim.

Since the purpose of punitive damages is not compensation of a plaintiff but punishment of the defendant and deterrence, punitive damages can be awarded only for conduct involving some element of outrage. *Hutchinson v. Luddy*, 582 Pa. 114, 870 A.2d 766 (2005). For that reason, Pennsylvania Supreme Court decisions establish that "punitive damages are an 'extreme remedy' available in only the most exceptional matters." *Wagner v. Onofrey*, 2006 Pa. Dist. & Cnty. Dec. LEXIS 333, *11 (Pa. Com. Pl. 2006) (citing *Phillips v. Cricket Lighters*, 584 Pa. 179, 188, 883 A.2d 439, 445 (2005)). "In fact, punitive damages are specifically designed to heap an additional punishment on a defendant who is found to have acted in a fashion which is particularly egregious." *Wagner* at *12.

Punitive damages may not be awarded for misconduct that constitutes ordinary negligence such as inadvertence, mistake and errors of judgment. *Martin v. Johns-Manville Corp.*, 494 A.2d 1088, 1097 (Pa. 1985); *McDaniel v. Merck, Sharp & Dohme*, 533 A.2d 436, 437 (Pa. Super. 1987). An award of punitive damages must be supported by evidence of conduct more serious than the mere commission of the underlying tort. *Allstate Ins. Co. v. A.M. Pugh Assoc., Inc.*, 604 F. Supp. 85, 99 (M.D. Pa. 1984).

Specifically, with regard to punitive damages in the context of claims against health care providers, the Medical Care and Reduction of Error (MCARE) Act permits punitive damages only to be awarded as follows:

- (a) Award. -- Punitive damages may be awarded for conduct that is the result of the health care provider's willful or wanton conduct or reckless indifference to the rights of others. In assessing punitive damages, the trier of fact can properly consider the character of the health care provider's act, the nature and extent of the harm to the patient that the health care provider caused or intended to cause and the wealth of the health care provider.
- (b) Gross Negligence. -- A showing of gross negligence is insufficient to support an award of punitive damages.

41 P.S. §1303.505.

The Supreme Court has made clear that when assessing the propriety of the imposition of punitive damages, "the state of mind of the actor is vital. The act or failure to act, must be intentional, reckless or malicious." *Hutchinson, supra* at 770. An appreciation of the risk is a necessary element of the mental state required for the imposition of punitive damages. *Id.* at 772. Thus, "a punitive damages claim must be supported by evidence sufficient to establish that (1) a defendant had a subjective appreciation of the risk of harm to which the plaintiff was exposed and that (2) he acted, or failed to act, as the case may be, in conscious disregard of that risk." *Id.*

Since professional negligence actions involve allegations that health care professionals deviated from the governing standard of care, punitive damages are generally not recoverable in malpractice actions unless the medical provider's deviation from the applicable standard of care is so egregious as to evince a conscious or reckless disregard of a patent risk of harm to the patient. *Wagner, supra*.

Where the facts as averred show nothing more than negligence, a lapse in judgment, or mere inadvertence, courts in Pennsylvania have dismissed pleas and claims for punitive damages, often at the pleadings stage of litigation and even if the complaint alleged severe injuries or death. *See, e.g., Brownawell v. Bryan*, 40 Pa. D. & C.3d 604, 606 (Pa. Com. Pl. 1985) (dismissing punitive damages claim where a plaintiff alleged that a physician negligently performed a spinal fusion surgery that left the plaintiff with severe neurological defects, and noting that “**the mere pleading of outrageous conduct** does not, of course, satisfy the requirement stating facts which, if proven, would form a basis for a jury concluding that the conduct was such that an award of punitive damages was warranted.”) (emphasis added); *Wagner, supra* at *11 (contentions that physician failed to prescribe antibiotics, order certain tests or request an infectious disease consult constituted “nothing more than ordinary negligence and are insufficient to support an award of punitive damages.”); *McCardle v. Aldinger*, 5 Pa. D. & C.4th 421, 428 (Pa. Com. Pl. 1996) (sustaining preliminary objections and dismissing claim for punitive damages where the plaintiff alleged negligence in the prenatal care of her child that led to the child was stillborn and holding that “[i]t is not the outcome of the alleged negligence that is of consideration, but rather the alleged conduct of defendants that is at issue.”); *Flurer v. Pocono Medical Ctr.*, 15 Pa. D. & C.4th 645, 670 (Pa. Com. Pl. 1992) (sustaining preliminary objections and finding that plaintiffs were not “capable of pleading the requisite behavior” for an award of punitive damages where a hospital allegedly failed

to properly utilize a fetal monitor on a pregnant woman who was involved in a serious car accident and thereafter delivered a stillborn child).

Conversely, punitive damages have been reserved for those situations that are truly egregious and utterly outrageous, and typically involve aggravating or other factors that evince a particularly reckless mind or evil motive. *See, e.g., Medvez v. Choi*, 569 F.2d 1221, 1227-30 (3rd Cir. 1987) (anesthesiologist who abandoned patient on operating room table and left room for a lunch break without securing a suitable replacement could be liable for punitive damages to patient who suffered irreversible paralysis from anesthesia complication that developed during his absence); *Hoffman v. Memorial Osteopathic Hospital*, 492 A.2d 1382, 386-87 (Pa. Super. 1985) (evidence that emergency room physician allowed Guillain-Barre Syndrome patient suffering from neurological paralysis to remain crying and immobile on floor for two hours as physician repeatedly stepped over patient was sufficient to support punitive damages claim); *Guernsey v. County Living Personal Care Home, Inc.*, 2006 U.S. Dist. LEXIS 31450, 2006 WL 1412765 (M.D. Pa. 2006) (punitive damages recoverable from nursing home officials who allowed resident to have access to room of 86-year old Alzheimer's patient where he repeatedly raped her, since nursing home was aware of resident's prior criminal convictions for sex registration as a sexual offender under Megan's Law, and his prior instances of grabbing and kissing staff); *Lawrence v. Kunkle*, 75 D. & C. 4th 370 (Pa. Com. Pl. 2005) (patient could maintain punitive damages claim against physician who refused to perform emergency surgery because patient did not have medical insurance even though physician knew that patient would likely suffer permanent neurologic and functional deficits if surgery was delayed).

All of the cases in the paragraph above set forth examples of egregious conduct, completely inapposite to the facts of the instant case. The facts underlying Plaintiffs' bare assertions of

reckless, outrageous or similar behavior do not even remotely meet the requisite standard under Pennsylvania law that would permit an award of punitive damages. Even assuming the allegations in the Complaint were true for the purposes of this argument only, the outcome in this case was not the result of any intentional wrongdoing or deliberate misconduct on the part of Moving Defendants or any medical provider at Pennsylvania Hospital, nor does the Complaint contain any such allegations.

Additionally, pursuant to § 505(c) of the MCARE Act, punitive damages are specifically restricted in claims involving vicarious liability:

(c) Vicarious liability. -- Punitive damages shall not be awarded against a healthcare provider who is only vicariously liable for the actions of its agent that caused the injury unless it can be shown by a preponderance of the evidence that the party knew of and allowed the conduct of its agent that resulted in an award of punitive damages.

40 P.S. §1303.505(c). Plaintiffs allege in this action that unidentified “staff” fed M.E. Similac and/or Enfamil at Pennsylvania Hospital shortly after his birth and failed to warn Plaintiff-parent of the alleged risks of such products. See Exhibit “B,” ¶ 12. Even if such actions were claimed to be egregious or malicious such that punitive damages were permissible, which is denied for the reasons stated above, Plaintiffs must allege facts to establish that Moving Defendants had actual knowledge of the alleged wrongful conduct and nevertheless allowed it. *See Zazzera v. Roche*, 54 D. & C. 4th 225, 238 (Pa. Com. Pl. 2001); *Dean Witter Reynolds, Inc. v. Genteel*, 499 A.2d 637 (Pa. Super. 1985). In this matter, Plaintiffs have failed to plead any facts to suggest that Moving Defendants were aware of any alleged misconduct by any individual alleged to be an agent and allowed such conduct to continue.

For all these reasons, Plaintiffs’ demand for punitive damages must be stricken with prejudice as to Moving Defendants, along with all allegations of reckless and similar conduct.

E. MOTION TO DISMISS PLAINTIFF-PARENT'S CLAIMS

1. Plaintiff-Parent has Failed to State a Cause of Action

Plaintiff-parent seeks to recover damages in her own right and as the parent and natural guardian of M.E. Plaintiffs' Amended Complaint includes allegations in each count asserted as to Moving Defendants in which it is averred that Plaintiff-parent "suffered significant emotional distress, loss of income, and/or other harms. Her life has been significantly altered by the Injured Infant's injuries." *See* Exhibit "B," ¶¶ 142, 155 and 163. However, no specific cause of action is asserted as to any damages sought by Plaintiff-parent in her own right, who is not alleged in the Amended Complaint to have suffered any physical injuries as a result of the alleged negligent conduct of Moving Defendants. For this reason, Plaintiff-parent's claim should be dismissed.

2. Plaintiffs are Required to Plead Separate Claims Pursuant to Pa.R.C.P. 1020

Further, even if Plaintiff-parent had properly articulated a cause of action in the Amended Complaint to allow her to recover damages in her own right, the Amended Complaint should be stricken pursuant to Pa.R.C.P. 1020(b), which provides as follows:

If persons join as plaintiffs under Rules 2228, 2229(a) or (e), the complaint shall state the cause of action, any special damage, and the demand for relief of each plaintiff in a separate count, preceded by a heading naming the parties to the causes of action therein set forth.

Accordingly, it is improper for Plaintiffs to plead in a single count claims on behalf of both the Plaintiff-minor and the Plaintiff-parent, as was done in the Amended Complaint filed herein. Claims on behalf of each of the Plaintiffs must be set forth in separate counts of the Amended Complaint, specifically identifying the cause of action asserted and relief sought in each count.

3. Plaintiff-Parent's Claim Is Precluded Pursuant to the Statute of Limitations

Although the statute of limitations for claims asserted on behalf of minors are tolled until the age of majority, Plaintiff-parent's claims were not similarly tolled and were required to have been brought within two years of the alleged injury. *See Hathi v. Krewstown Park Apts*, 561 A.2d 1261 (Pa. Super. 1989); 42 Pa.C.S. § 5524. Plaintiffs allege that M.E. was born on September 28, 2007, was fed the Defendant manufacturers' products shortly after his birth, and developed NEC shortly thereafter. *See* Exhibit "B," ¶¶ 11-13. Thus, since the Amended Complaint herein was filed on March 24, 2022, Plaintiff-parent's claims herein are clearly time-barred based on the applicable statute of limitations.

In an attempt to circumvent the statute of limitations issues for the Plaintiff-parent, Plaintiffs go to great lengths in their Amended Complaint to essentially assert that Plaintiff-parent's claims are somehow preserved by way of the discovery rule. *See*, Exhibit "B" ¶¶ 24 – 39. More specifically, Plaintiffs have attempted to invoke the Pennsylvania "discovery rule" by arguing that the applicable statute of limitations did not commence until some later date that has not even been plead, due to alleged concealment and misrepresentations. *See* Exhibit "B" at ¶24 - 39.

The discovery rule is a recognized exception to the general rule that a statute of limitations begins to run from the date that a negligent act occurs. The discovery rule provides that where the existence of the injury is not known to the complaining party and such knowledge cannot reasonably be ascertained within the prescribed period, the period of limitation does not begin to run until discovery of the injury is reasonably possible. *Hayward v. Medical Center of Beaver County*, 608 A.2d 1040, 1043 (Pa. 1992). However, in accordance with the discovery rule, a plaintiff need not know the precise medical cause of the injury for the statute of limitations to begin

running; she need only to have known that an injury occurred. *Groover v. Riddle Memorial Hospital*, 357 Pa. Super. 420, 516 A.2d 53 (1986).

Any contention by Plaintiffs that the statute of limitations must be tolled until such time that a plaintiff first suspected that there had been medical negligence with regard to her infant's treatment must similarly be rejected. It is well established in Pennsylvania that a plaintiff need not know the precise extent of injuries before the statutory period begins to run. *Levenson v. Souser*, 384 Pa. Super. 132, 557 A.2d 1081, 1090 (1989). Further, it is well settled law that, in accordance with the discovery rule, a plaintiff need not know that she has a cause of action or suspects there has been negligence before the statute of limitations commences. *Colonna v. Rice*, 664 A.2d 979, 981 (Pa. Super. 1995); *Bigansky v. Thomas Jefferson Univ. Hosp.*, 658 A.2d 423, 427, 431 n.5 (Pa. Super. 1995); *Brooks v. Sagovia*, 636 A.2d 1201, 1204 (Pa. Super. 1994); *E.J.M. v. Archdiocese of Phila.*, 622 A.2d 1388, 1394 (Pa. Super. 1993); *DeMartino v. Albert Einstein Med. Center*, 460 A.2d 295, 298-299 (Pa. Super. 1983). Indeed, it has been expressly held that “[k]nowledge of the negligence is not part of the discovery rule.” *DeMartino, supra*, 460 A.2d at 299. A plaintiff need only know that there was an injury and who caused that injury, a plaintiff need not know the full extent of the injury or even suspect negligence. *Nicolaou v. Martin*, 195 A.3d 880, 892-93 (Pa. 2018); *Gleason v. Borough of Moosic*, 15 A.3d 479, 484 (Pa. 2011); *Wilson v. El-Daief*, 964 A.2d 354, 364 (Pa. 2009).

Based upon the facts plead by Plaintiffs, M.E. is alleged to have developed NEC shortly after his birth. See Exhibit “B” ¶¶11 – 14. Accordingly, Plaintiff-parent knew of an injury in 2007, making any claim in her own right clearly time barred, regardless of whether she knew the extent of any claimed injury and/or when she suspected that the injury was caused by negligence.

The statute of limitations for Plaintiff-parent had clearly expired by the time this action was commenced on March 24, 2022.

**MOTION TO STRIKE PLAINTIFFS' COMPLAINT FOR FAILURE TO
COMPLY WITH Pa.R.C.P. 1024**


Pennsylvania Rule of Civil Procedure 1024(a) requires verification of every pleading containing a factual averment based upon the signer's personal knowledge or information and belief. Rule 1024(c) requires that the verification be made by one or more of the parties filing the pleading. In this case, Plaintiffs' Amended Complaint is unverified in violation of Rule 1024. *See* Exhibit "B." Accordingly, the Amended Complaint should be stricken for lack of an appropriate verification.

V, REQUESTED RELIEF

For the foregoing reasons, Defendants The Pennsylvania Hospital of the University of Pennsylvania Health System d/b/a Pennsylvania Hospital and The Trustees of the University of Pennsylvania d/b/a Penn Medicine respectfully request that this Honorable Court sustain their Preliminary Objections and enter the attached Order.


BURNS WHITE LLC

BY: _____


JAMES A. YOUNG, ESQ.
RICHARD S. MARGULIES, ESQ.
Attorneys for Defendants,
The Pennsylvania Hospital of the University of
Pennsylvania Health System d/b/a Pennsylvania
Hospital and The Trustees of the University of
Pennsylvania d/b/a Penn Medicine

CERTIFICATE OF SERVICE

I, Richard S. Margulies, Esquire, do hereby certify that on this day I caused a true and correct copy of the foregoing Preliminary Objections of Defendants The Pennsylvania Hospital of the University of Pennsylvania Health System d/b/a Pennsylvania Hospital and The Trustees of the University of Pennsylvania d/b/a Penn Medicine to Plaintiffs' Amended Complaint, to be served via the electronic filing system to all counsel of record.

BY: 
RICHARD S. MARGULIES, ESQ.

Dated: September 27, 2023

Court of Common Pleas of Philadelphia County
Trial Division
Civil Cover Sheet

For Prothonotary Use Only (Docket Number)

MARCH 2022

E-Filing Number: 2203055175

002617
Filed and Attested by the
Office of Judicial Records
27 SEP 2023 02:15 pm
S. GILLIAM

PLAINTIFF'S NAME ALICE STILLS		DEFENDANT'S NAME MEAD JOHNSON NUTRITION COMPANY	
PLAINTIFF'S ADDRESS 656 N. CONESTOGA ST. PHILADELPHIA PA 19131		DEFENDANT'S ADDRESS ILLINOIS CORPORATION SERVICE C 801 ADLAI STEVENSON DR. SPRINGFIELD IL 62703	
PLAINTIFF'S NAME M E		DEFENDANT'S NAME THE PA HOSPITAL OF THE UNIVERSITY OF PA HEALTH SYSTEM, ALIAS: PENNSYLVANIA HOSPITAL	
PLAINTIFF'S ADDRESS 656 N. CONESTOGA ST. PHILADELPHIA PA 19131		DEFENDANT'S ADDRESS 3400 CIVIC CENTER BLVD. PHILADELPHIA PA 19104	
PLAINTIFF'S NAME		DEFENDANT'S NAME THE TRUSTEES OF THE UNIVERSITY OF PENNSYLVANIA, ALIAS: PENN MEDICINE	
PLAINTIFF'S ADDRESS		DEFENDANT'S ADDRESS 133 SOUTH 36TH ST. PHILADELPHIA PA 19104	
TOTAL NUMBER OF PLAINTIFFS 2	TOTAL NUMBER OF DEFENDANTS 5	COMMENCEMENT OF ACTION <input checked="" type="checkbox"/> Complaint <input type="checkbox"/> Petition Action <input type="checkbox"/> Notice of Appeal <input type="checkbox"/> Writ of Summons <input type="checkbox"/> Transfer From Other Jurisdictions	
AMOUNT IN CONTROVERSY <input type="checkbox"/> \$50,000.00 or less <input checked="" type="checkbox"/> More than \$50,000.00	COURT PROGRAMS <input type="checkbox"/> Arbitration <input type="checkbox"/> Mass Tort <input type="checkbox"/> Commerce <input type="checkbox"/> Settlement <input checked="" type="checkbox"/> Jury <input type="checkbox"/> Savings Action <input type="checkbox"/> Minor Court Appeal <input type="checkbox"/> Minors <input type="checkbox"/> Non-Jury <input type="checkbox"/> Petition <input type="checkbox"/> Statutory Appeals <input type="checkbox"/> W/D/Survival <input type="checkbox"/> Other:		
CASE TYPE AND CODE 2P - PRODUCT LIABILITY			
STATUTORY BASIS FOR CAUSE OF ACTION			
RELATED PENDING CASES (LIST BY CASE CAPTION AND DOCKET NUMBER)		IS CASE SUBJECT TO COORDINATION ORDER? YES NO	
		<p>FILED PROPROTHY MAR 24 2022 S. RICE</p>	
<p>TO THE PROTHONOTARY:</p> <p>Kindly enter my appearance on behalf of Plaintiff/Petitioner/Appellant: <u>ALICE STILLS , M E</u></p> <p>Papers may be served at the address set forth below.</p>			
NAME OF PLAINTIFF'S/PETITIONER'S/APPELLANT'S ATTORNEY TRACY A. FINKEN		ADDRESS ONE LOGAN SQUARE 130 N. 18TH ST. SUITE 1600 PHILADELPHIA PA 19103	
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SUPREME COURT IDENTIFICATION NO. 82258		E-MAIL ADDRESS tfinken@anapolweiss.com	
SIGNATURE OF FILING ATTORNEY OR PARTY TRACY FINKEN		DATE SUBMITTED Thursday, March 24, 2022, 04:41 pm	

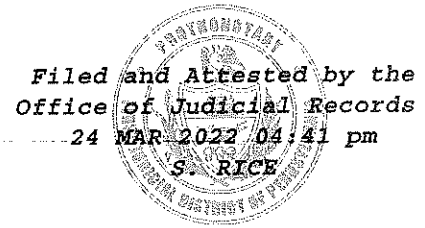
FINAL COPY (Approved by the Prothonotary Clerk)

Case ID: 220302617
Control No.: 23096271

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Plaintiffs

v.

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801 Adlai Stevenson Drive
Springfield, IL 62703

MEAD JOHNSON NUTRITION COMPANY
Illinois Corporation Service Co.
801 Adlai Stevenson Drive
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ABBOTT LABORATORIES
CT Corporation System
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COURT OF COMMON PLEAS
PHILADELPHIA COUNTY

CIVIL ACTION

NO.

THE PENNSYLVANIA HOSPITAL OF
THE UNIVERSITY OF PENNSYLVANIA
HEALTH SYSTEM d/b/a PENNSYLVANIA
HOSPITAL
3400 Civic Center Blvd.
Philadelphia, PA 19104

THE TRUSTEES OF THE UNIVERSITY OF
PENNSYLVANIA d/b/a PENN MEDICINE
133 South 36th Street
Philadelphia, PA 19104

Defendants

JURY TRIAL DEMANDED

COMPLAINT IN CIVIL ACTION

NOTICE TO DEFEND

NOTICE

You have been sued in court. If you wish to defend against the claims set forth in the following pages, you must take action within twenty (20) days after this complaint and notice are served, by entering a written appearance personally or by attorney and filing in writing with the court your defenses or objections to the claims set forth against you by the court without further notice for any money claimed in the complaint or for any other claim or relief requested by the plaintiff. You may lose money or property or other rights important to you.

YOU SHOULD TAKE THIS PAPER TO YOUR LAWYER AT ONCE. IF YOU DO NOT HAVE A LAWYER OR CANNOT AFFORD ONE, GO TO OR TELEPHONE THE OFFICE SET FORTH BELOW TO FIND OUT WHERE YOU CAN GET LEGAL HELP.

PHILADELPHIA BAR ASSOCIATION
LAWYER REFERRAL AND INFORMATION SERVICE
ONE READING CENTER
PHILADELPHIA, PA 19107
TELEPHONE: (215) 238-1701

AVISO

Le han demandado a usted en la corte. Si usted quiere defenderse de estas demandas expuestas las páginas siguientes, usted tiene veinte (20) días de plazo al partir de la fecha de la demanda y la notificación. Hace falta asentar una comparencia escrita o en persona o con un abogado y entregar a la corte en forma escrita sus defensas o sus objeciones a las demandas en contra de su persona. Sea avisado que si usted no se defiende, la corte tomará medidas y puede continuar la demanda en contra suya sin previo aviso o notificación. Además, la corte puede decidir a favor del demandante y requiere que usted cumpla con todas las provisiones de esta demanda. Usted puese perder dinero o sus propiedades u otros derechos importantes para usted.

LLEVE ESTA DEMANDA A UN ABOGADO INMEDIATAMENTE. SI NO TIENE ABOGADO O SI NO TIENE EL DINERO SUFICIENTE DE PAGAR TAL SERVICIO, VAYA EN PERSONA O LLAME POR TELEPHONO A LA OFICINA CUYA DIRECCION SE ENCUENTRA ESCRITA ABAJO PARA AVERIGUAR DONDE SE PUEDE CONSEGUIR ASISTENCIA LEGAL.

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PLAINTIFFS

V.

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MEAD JOHNSON NUTRITION COMPANY
ILLINOIS CORPORATION SERVICE Co.
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THE UNIVERSITY OF PENNSYLVANIA
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COURT OF COMMON PLEAS
PHILADELPHIA COUNTY

CIVIL ACTION

NO.

HOSPITAL
3400 CIVIC CENTER BLVD.
PHILADELPHIA, PA 19104

**THE TRUSTEES OF THE UNIVERSITY OF
PENNSYLVANIA D/B/A PENN MEDICINE
133 SOUTH 36TH STREET
PHILADELPHIA, PA 19104**

DEFENDANTS

JURY TRIAL DEMANDED

COMPLAINT

Plaintiff brings this Complaint and Demand for Jury Trial (the “Complaint”) against Mead Johnson & Company, LLC, Mead Johnson Nutrition Company, and Abbott Laboratories (collectively “the Defendant Manufacturers”), and The Trustees of the University of Pennsylvania d/b/a Penn Medicine and Pennsylvania Hospital of the University of Pennsylvania Health System d/b/a Pennsylvania Hospital (collectively “Penn Medicine” or “Pennsylvania Hospital”), together “Defendants.” Plaintiff alleges the following upon personal knowledge as to Plaintiff’s own acts and experiences and upon information and belief, including investigation conducted by Plaintiff’s attorneys, as to all other matters.

I. INTRODUCTION

1. This action arises out of the injuries suffered by a premature infant (the “Injured Infant”) who was given the Defendant Manufacturers’ cow’s milk-based infant feeding products at Pennsylvania Hospital. Pennsylvania Hospital, managed by Penn Medicine, acquired and supplied the Defendant Manufacturers’ products to the Injured Infant and negligently failed to warn of their unreasonably dangerous properties in a reasonable manner. This caused the Injured Infant to develop necrotizing enterocolitis (“NEC”), a life-altering and potentially deadly disease that largely affects premature babies who are given cow’s milk-based feeding products. As a result,

the Injured Infant was seriously injured, resulting in long term health effects and accompanying harm to their parent (“the Plaintiff Parent”).

2. Plaintiff brings these causes of action against Defendants to recover for injuries that are the direct and proximate result of the Injured Infant’s consumption of the Defendant Manufacturers’ unreasonably dangerous cow’s milk-based infant feeding products, which were acquired and supplied without adequate warning to the Injured Infant at Pennsylvania Hospital, owned and operated by Penn Medicine.

II. PARTIES

3. Plaintiff Alice Stills is a natural adult person and a resident of Pennsylvania. Ms. Stills is the parent and natural guardian of M.E., a minor. Ms. Stills’ address is 656 N Conestoga Street, Philadelphia, Pennsylvania 19131.

4. Defendant Mead Johnson Nutrition Company is a corporation, incorporated under the laws of the State of Delaware. Its principal place of business is Illinois. Defendant Mead Johnson & Company, LLC, is a limited liability company, organized under the laws of the State of Delaware. Its citizenship is that of its sole member, Mead Johnson Nutrition Company. Defendants Mead Johnson Nutrition Company and Mead Johnson & Company, LLC, (together, “Mead”) are manufacturers of cow’s milk-based infant feeding products and market many of these products under the “Enfamil” brand name.

5. Defendant Abbott Laboratories (“Abbott”) is a corporation, incorporated under the laws of the State of Illinois. Its principal place of business is in Illinois. Abbott is a manufacturer of cow’s milk-based infant feeding products and markets many of its products under the “Similac” brand name.

6. Defendant The Pennsylvania Hospital of the University of Pennsylvania Health System d/b/a Pennsylvania Hospital is a non-profit corporation incorporated and registered to do business under the laws of the Commonwealth of Pennsylvania. Its principal place of business is Philadelphia, Pennsylvania. Pennsylvania Hospital is a registered name of The Pennsylvania Hospital of the University of Pennsylvania Health System. The sole member of The Pennsylvania Hospital of the University of Pennsylvania Health System is The Trustees of the University of Pennsylvania.

7. Defendant The Trustees of the University of Pennsylvania d/b/a Penn Medicine is a non-profit corporation registered to do business in the Commonwealth of Pennsylvania. Its principal place of business is Philadelphia, Pennsylvania. Penn Medicine is a registered name of The Trustees of the University of Pennsylvania.

III. JURISDICTION AND VENUE

8. This Court has jurisdiction in this matter pursuant to 42 Pa. C.S.A. § 931. Defendants conduct authorized business in the Commonwealth of Pennsylvania. They have sufficient minimum contacts with and purposefully avail themselves of the markets of this Commonwealth. This suit arises out of Defendants' forum-related activities, such that the Court of Common Pleas of Philadelphia County's exercise of jurisdiction would be consistent with traditional notions of fair play and substantial justice.

9. Venue is proper in the Court of Common Pleas of Philadelphia County pursuant to Rules 1006(b), 1006(c)(1), and 2179(a) of the Pennsylvania Rules of Civil Procedure because Defendants are corporations or similar entities that regularly conduct business in Philadelphia County, which is also the county where Plaintiff's causes of action arose, and the county where the occurrences took place out of which Plaintiff's causes of action arose.

10. This action is not subject to the Compulsory Arbitration Program of the Court of Common Pleas of Philadelphia County because the amount in controversy, excluding interest and costs, is in excess of \$50,000.

IV. FACTUAL ALLEGATIONS

M.E.'s NEC Diagnosis

11. M.E. was born prematurely at Pennsylvania Hospital in Philadelphia, Pennsylvania on September 28, 2007.

12. Upon information and belief M.E. was fed Similac and/or Enfamil cow's milk-based products by staff at Pennsylvania Hospital from shortly after his birth.

13. Upon information and belief shortly after M.E. first ingested the Defendant Manufacturers' products, he developed NEC.

Cow's Milk-Based Feeding Products Are Known to Cause NEC

14. NEC is a devastating disease that is the most frequent and lethal gastrointestinal disorder affecting preterm infants. NEC develops when harmful bacteria breach the walls of the intestine, causing portions of the intestine to become inflamed and often to die. Once NEC develops, the condition can progress rapidly from mild feeding intolerance to systemic and fatal sepsis. Up to 30 percent of NEC-diagnosed infants die from the disease.

15. Preterm and low-birth-weight infants are especially susceptible to NEC because of their underdeveloped digestive systems. Extensive scientific research, including numerous randomized controlled trials, has confirmed that cow's milk-based feeding products cause NEC in preterm and low-birth-weight infants, which in turn may lead to other medical complications, surgeries, long-term health problems, and death.

16. For example, in one randomized, multicenter study of 926 preterm infants, NEC was six to ten times more common in exclusively cow's milk formula-fed babies than in exclusively breast milk-fed babies and three times more common in babies who received a combination of formula and breast milk. For babies born at more than 30 weeks gestation, NEC was 20 times more common in those only fed cow's milk formula than in those fed breast milk.

17. Another randomized controlled trial showed that preterm babies fed an exclusive breast milk-based diet were 90% less likely to develop surgical NEC (NEC that requires surgical treatment), compared to preterm babies fed a diet that included some cow's milk-based products.

18. Yet another study that analyzed the data from a 12-center randomized trial concluded that fortification of breast milk with a cow's milk-based fortifier resulted in a 4.2-fold increased risk of NEC and a 5.1-fold increased risk of surgical NEC or death, compared to fortification with a breast milk-based fortifier.

19. A Surgeon General report, The Surgeon General's Call to Action to Support Breastfeeding, warns that, "for vulnerable premature infants, formula feeding is associated with higher rates of necrotizing enterocolitis." The report also states that premature infants who are not breastfed are 138% more likely to develop NEC.

20. The American Academy of Pediatrics, "an organization of 67,000 pediatricians committed to the optimal physical, mental, and social health and well-being for all infants, children, adolescents, and young adults," has advised that all premature infants should be fed either their mother's milk or, if their mother's milk is unavailable, pasteurized human donor milk. This recommendation is based on the "potent benefits of human milk," including "lower rates of . . . NEC."

21. A multicenter, randomized, controlled trial found that premature and low-birth-weight infants fed an exclusive breast milk-based diet suffered NEC only 3% of the time while premature and low-birth-weight infants receiving cow's milk-based formula suffered NEC 21% of the time.

22. Another study conducted a randomized comparison of extremely preterm infants who were given either (a) a diet of breast milk fortified with a breast milk-based fortifier or (b) a diet containing variable amounts of cow's milk-based products. The babies given exclusively breast milk products suffered NEC 5% of the time. The babies given cow's milk products suffered NEC 17% of the time.

Safer, Nutritionally Superior Alternatives To Cow's Milk-Based Products Exist

23. A range of options are available that allow preterm and low-birth-weight infants to be fed exclusively human milk-based nutrition. For example, in addition to the mother's own milk, an established network delivers pasteurized donor breast milk to hospitals nationwide. Moreover, hospitals have access to shelf-stable formula and fortifiers derived from pasteurized breast milk.

24. A diet based exclusively on breast milk and breast milk fortifiers provides all the nutrition necessary to support premature and low-birth-weight infants without the elevated risk of NEC associated with cow's milk-based products. For example, in a study analyzing preterm infants who were fed an exclusive breast milk-based diet until they reached 34 weeks, all 104 infants exceeded standard growth targets and met length and head-circumference growth targets, demonstrating that infants can achieve and mostly exceed targeted growth standards when receiving an exclusive breast milk-based diet. This is particularly true given the ability of breast milk-based fortifiers to provide the additional nutritional supplements necessary for adequate growth while receiving the protective benefits of a breast milk diet.

25. The Defendant Manufacturers' products not only pose a threat to infants' health, but also displace the breast milk they could otherwise receive. This displacement only increases infants' vulnerability to NEC, as studies show that breast milk protects against the disease. For example, a study analyzing 1,587 infants across multiple institutions concluded that an exclusive breast milk-based diet is associated with significant benefits for extremely premature infants and that it produced no feeding-related adverse outcomes.

26. For the above reasons, experts acknowledge that breast milk is the best source of nutrition for preterm infants and those at risk for NEC. Breast milk-based nutrition nourishes infants while creating a significantly lower risk of NEC.

27. At the time the Injured Infant was fed the Defendant Manufacturers' products, the science clearly demonstrated to Defendants that these products cause NEC and greatly increase the likelihood that a baby will develop NEC, leading to severe injury and often death.

28. Despite the scientific consensus that the Defendant Manufacturers' cow's milk-based products present a dire threat to the health and development of preterm infants, the Defendant Manufacturers have made no changes to their products or the products' packaging, guidelines, instructions, or warnings. Instead, they have continued to sell their unreasonably dangerous products. In addition, they incentivize hospitals that know the risks to use their products by providing them to the hospital for free or at a significant discount, in order that vulnerable infants and their families will become accustomed to using their products before discharge.

***The Defendant Manufacturers' False And Misleading Marketing
Regarding Cow's Milk-Based Infant Products***

29. Abbott and Mead have aggressively marketed their cow's milk-based products as medically endorsed and nutritionally equivalent alternatives to breast milk, including prior to the Injured Infant's birth.

30. Abbott's and Mead's marketing approach includes targeting the parents of preterm infants while they are still in the hospital with messages that the Defendant Manufacturers' cow's milk formulas and fortifiers are necessary for the growth and development of their vulnerable children. Often these tactics implicitly discourage mothers from breastfeeding, which reduces the mother's supply of breast milk. None of the Defendant Manufacturers' marketing materials, including their promotional websites, reference the science showing how significantly their products increase the risk of NEC.

31. Numerous studies have shown the detrimental impact of formula advertising on the rates of initiation and continuation of breastfeeding, including studies that show that as "hand feeding" (non-breastfeeding) advertisements increase, reported breastfeeding rates decrease in the following year.

32. Undoubtedly aware of the impact of their advertising, the Defendant Manufacturers, along with other formula manufacturers, are willing to spend massive sums to disseminate their message, with one study estimating that formula manufacturers collectively spent \$4.48 billion on marketing and promotion in 2014 alone.

33. Recognizing the abuse and dangers of infant formula marketing, in 1981, the World Health Assembly—the decision-making body of the World Health Organization—developed the International Code of Marketing of Breast-milk Substitutes ("the Code"), which required companies to acknowledge the superiority of breast milk, the negative effect on breastfeeding of introducing partial bottle-feeding, and the difficulty of reversing the decision not to breastfeed. The Code also forbade advertising or other forms of promotion of formula to the general public, as well as providing sample products to mothers or members of their families.

34. While Abbott and Mead acknowledge the Code on their websites and claim to support the effort to encourage mothers to breastfeed for as long as possible, this is little more than lip service. Instead, the Defendant Manufacturers' aggressive marketing exploits new parents' darkest fears—that the nutrition they are supplying to their child will not provide the best chance of survival—while wholly failing to warn that their products come with a significantly increased risk of NEC.

35. For example, Abbott's website, on a page titled "Infant Formula Marketing," states: "We agree with the World Health Organization that breastfeeding provides the best nutrition for babies, and we support its goal to increase breastfeeding. We also recognize that for infants who aren't breastfed—for medical reasons or otherwise—infant formula is the only appropriate, safe alternative to meet babies' nutritional needs." This statement ignores the existence of donor milk, as well as human milk-based formula.

36. Abbott markets and sells multiple products specifically targeting preterm and low-birth-weight infants, including Liquid Protein Fortifier, Similac NeoSure, Similac Human Milk Fortifiers, Similac Special Care 20, Similac Special Care 24, Similac Special Care 24 High Protein, and Similac Special Care 30. In advertising these products, Abbott emphasizes the products' purported ability to assist underdeveloped babies in reaching their growth targets. For example, on the since-edited webpage regarding Similac NeoSure, Abbott noted: "Your premature baby didn't get her full 9 months in the womb, so her body is working hard to catch up. During her first full year, feed her Similac NeoSure, a nutrient-enriched formula for babies who were born prematurely, and help support her development." Yet, no mention was made of the accompanying significantly increased risk of NEC. At some point, the website was edited to remove this statement. However, upon information and belief, the statement remained on the website until at least December 2020.

37. Mead markets and sells multiple products specifically targeting premature infants, including Enfamil NeuroPro EnfaCare Infant Formula, Enfamil Premature Infant Formula 24 Cal High Protein, Enfamil Premature Infant Formula 30 Cal with Iron, Enfamil Premature Infant Formula 24 Cal with Iron, Enfamil Premature Infant Formula 20 Cal with Iron, Enfamil 24 Cal Infant Formula, and Enfamil Human Milk Fortifier (acidified liquid and powder). In advertising these products, Mead emphasizes the purported similarities between its formula and breast milk, while failing to include any information about the nutritional deficits and dangers that accompany formula use. For example, the since-edited webpage for Enfamil Enfacare stated: “Premature babies fed Enfamil® formulas during the first year have achieved catch-up growth similar to that of full term, breastfed infants” and noted that Enfamil formulas include “expert-recommended levels of DHA and ARA (important fatty acids found naturally in breast milk) to support brain and eye development.”

38. One Enfamil advertisement, introducing a new product line called Enfamil NeuroPro, is entirely focused on favorably comparing Enfamil’s formula to breast milk, without any mention of the product’s extreme risks. Indeed, the terms “human milk” and “breast milk” are used 13 times in the advertisement, including in such statements as “for decades human milk has inspired the advancements in Enfamil formulas and now through extensive global research, we are taking an even closer look at human milk” and “only Enfamil NeuroPro has a fat blend of MFGM and DHA previously found only in breast milk.” The webpage for the product has made similar manipulative claims, stating “Enfamil is backed by decades of breast milk research and multiple clinical studies” and it claims that “to create our best formulas, we collaborated on some of the most extensive breast milk studies to date[.]”

39. Formula manufacturers have long used their relationships with hospitals and the discharge process to encourage parents to substitute formula for breast milk. They offer free or reduced-cost formula to hospitals for use with infants before discharge. And they offer free formula, coupons, and even entire gift baskets to parents before their infants' discharge from the NICU or hospital.

40. Through this early targeting, the Defendant Manufacturers create brand loyalty under the guise of a "medical blessing," in hopes that new parents continue to use formula after they leave the hospital, resulting in increased expense for parents, significantly increased risk for babies, and increased profit for the Defendant Manufacturers. The Defendant Manufacturers' giveaways and gift baskets send confusing signals to mothers who are simultaneously being encouraged to breastfeed by their healthcare professionals, and they have been shown to negatively impact breastfeeding rates.

41. Further, when the Defendant Manufacturers recognized a shift in the medical community towards an exclusive breast milk-based diet for premature infants, Abbott developed a product called "Similac Human Milk Fortifier," and Mead developed "Enfamil Human Milk Fortifier." These names are misleading in that they suggest that the products are derived from breast milk, when, in fact, they are cow's milk-based products. One study, for example, found that only 8.8 percent of parents surveyed in the NICU interpreted "human milk fortifier" as potentially meaning a cow's milk-based product. The packaging appears as:



42. The Defendant Manufacturers have designed powerful misleading marketing campaigns to deceive parents into believing that: (1) cow's milk-based products are safe, including for preterm infants; (2) cow's milk-based products are equal, or even superior, substitutes to breast milk; (3) cow's milk-based products are necessary for proper growth and development of preterm infants; and (4) physicians consider the Defendant Manufacturers' cow's milk-based products to be a first choice. This marketing scheme is employed despite all Defendants knowing of and failing to warn of the extreme risk of NEC and death that cow's milk-based products pose to preterm infants like the Injured Infant.

The Defendant Manufacturers' Inadequate Warnings

43. Although Mead promotes an aggressive marketing campaign designed to convince parents that its cow's milk-based products are safe and necessary for the growth of a premature infant, the product is in fact extremely dangerous for premature infants. Enfamil products significantly increase the chances of a premature infant developing potentially fatal NEC.

44. The Enfamil products Mead markets specifically for premature infants are commercially available at retail locations and online. No prescription is necessary.

45. Despite knowing of the risk of NEC, the packaging of Mead's products does not warn of the significantly increased risk of NEC (and resulting medical conditions, and/or death) associated with Mead's products, or of the magnitude of this increased risk. Mead likewise did not provide instructions or guidance for how to avoid NEC.

46. Mead cites no medical literature or research to guide the use of its products.

47. Despite knowing of the risk of NEC, Mead did not warn of the significantly increased risk of NEC (and resulting medical conditions, and/or death) associated with its products, or of the magnitude of this increased risk. Mead likewise did not provide instructions or guidance for how to avoid NEC.

48. Mead deceived the public, parents, physicians, other medical professionals, and medical staff into believing that Enfamil products were a safe and necessary alternative, supplement and/or substitute to breast milk.

49. Despite knowing that its products were being fed to premature infants, often without the parents' informed consent, Mead failed to require or recommend that medical professionals inform parents of the significant risk of NEC or to require that parental consent be obtained prior to the products being fed to their babies.

50. Like Mead, Abbott promotes an aggressive marketing campaign designed to make parents believe that its products are safe and necessary for the growth of premature infants, despite the products in fact being extremely dangerous for premature infants. Abbott's products significantly increase the chances of a premature infant getting potentially fatal NEC.

51. The products Abbott markets specifically for premature infants are available at retail locations and online. No prescription is necessary.

52. Despite knowing of the risk of NEC, Abbott did not warn of the significantly increased risk of NEC (and resulting medical conditions, and/or death) associated with its products, or of the magnitude of this increased risk. Abbott likewise did not provide instructions or guidance for how to avoid NEC.

53. Abbott deceived the public, parents, physicians, other medical professionals, and medical staff into believing that its products were a safe and necessary alternative, supplement and/or substitute to breast milk.

54. Despite knowing that its products were being fed to premature infants, often without the parents' informed consent, Abbott failed to require or recommend that medical professionals inform parents of the significant risk of NEC or to require that parental consent be obtained prior to the products being fed to their babies.

Penn Medicine's Failure to Warn

55. On information and belief, Penn Medicine, which operates Pennsylvania Hospital, was aware of the significantly increased risk of NEC and death associated with providing Abbott's and Mead's cow's milk-based products to its premature infant patients. It knew or should have known that feeding these cow's milk-based products can cause NEC in premature infants who otherwise would not have developed this devastating condition. However, instead of warning of those

dangers, or supplying breast milk-based feeding products to preterm infants like the Injured Infant, Penn Medicine has continued to source, distribute, and supply the Defendant Manufacturers' products in its hospitals without any adequate warning.

56. To that end, Penn Medicine has participated in studies designed to increase the use of donor milk while, at the same time, reducing formula feeding in neonates. The University of Pennsylvania School of Nursing, an affiliate of Penn Medicine, has conducted extensive research into the risks associated with feeding formula to premature infants. It recently partnered with the National Institute of Nursing Research to publish clinical determinations based on its experience "changing hospital systems and influencing policy," and its findings were unequivocal:

This is what we know about the science of human milk: it reduces the risk of necrotizing enterocolitis, reduces the risk of infection, [and] creates greater enteral feed tolerance and more rapid weaning from intravenous nutrition. . . .

Other Penn Medicine research has similarly concluded that "[h]uman milk decreases the incidence and severity of . . . necrotizing enterocolitis (NEC)."

57. Penn Medicine also purports to adhere to the tenets of the "Baby Friendly Hospital Initiative," which seeks to increase rates of breastfeeding initiation, exclusivity, and diet duration. The "Baby Friendly Hospital Initiative" specifically targets a reduction in the rates of NEC in preterm infants by encouraging implementation of exclusive breast milk diets among new mothers. Although Pennsylvania Hospital has maintained its "Baby Friendly" designation for years, it has not eliminated or restricted the use of formula or fortifier for preterm infants in its hospitals.

58. Finally, medical providers and staff at Penn Medicine have acknowledged the risks associated with providing the Defendant Manufacturers' cow's milk-based products to premature infant patients instead of breast milk-based nutrition. In an internal newsletter from 2012 touting donor milk programs, Penn Medicine acknowledged the benefits of a human milk-based diet, quoting a staff lactation consultant:

Donor milk is not inexpensive. It costs about \$4.25 per ounce, but the return on investment is huge. “Preemies given mother’s milk get discharged three to four days sooner and also have a six to 10 times lower risk of getting a gastrointestinal complication called necrotizing enterocolitis,” Carpenter said, adding that the infection can cost up to \$250,000 to treat. The average cost to provide a preemie with donor milk: \$125.

59. These statements demonstrate that Penn Medicine knew or should have known of the high increased risk of NEC for premature infants posed by the Defendant Manufacturers’ products.

60. Although Penn Medicine knew or should have known of the serious danger of the Defendant Manufacturers’ products, it has continued to purchase, supply, and distribute these products to preterm infants without providing full and adequate warnings of the attendant risks to parents, healthcare professionals, and other medical staff at its relevant facilities. As a result, the Injured Infant was fed the Defendant Manufacturers’ cow’s milk-based products at Pennsylvania Hospital, causing their injuries. This occurred even though hospitals across the country, including Pennsylvania Hospital, warn and obtain consent from parents before providing other safer forms of nutrition, such as donor breast milk.

61. Penn Medicine’s failure to warn of the risks posed by the Defendant Manufacturers’ products is entrenched (and compounded) by the financial benefits it accrues from its relationships with the Defendant Manufacturers. On information and belief, it has received the Defendant Manufacturers’ cow’s milk-based products for free or at a significant discount, and has granted their sales representatives access to its healthcare professionals and medical staff. These sales representatives have provided deceptive information that Penn Medicine reasonably knew or should have known would ultimately reach parents through those staff. This arrangement dovetails with the Defendant Manufacturers’ own marketing strategy, which aims to “sell and service” healthcare professionals and medical staff as a means of converting them into “extra salespersons.”

Safer Alternative Designs

62. The Defendant Manufacturers' cow's milk-based products made specifically for premature infants are unreasonably unsafe for those infants. The Defendant Manufacturers could have used pasteurized breast milk instead of cow's milk in their products, which would have produced a safer product.

63. Prolacta Bioscience manufactures and sells breast milk-based feeding products, specifically designed for preterm infants, which contain no cow's milk. This alternative design provides all the necessary nutrition for growth and development that cow's milk-based products provide, without the same unreasonably dangerous and deadly effects.

64. On information and belief, Abbott and Mead were aware of the significantly increased risk of NEC and death associated with their cow's milk-based products, and instead of warning of the dangers, or removing them altogether, Abbott and Mead have continued to use cow's milk as the foundation of their products.

CAUSES OF ACTION
COUNT I: STRICT LIABILITY FOR DESIGN DEFECT
(Against Abbott and Mead)

65. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.

66. Abbott and Mead, as the manufacturers and/or sellers of the products at issue in this litigation, owed a duty to the consuming public in general, and the Plaintiff Parent in particular, to manufacture, sell, and distribute their products in a manner that was not unreasonably dangerous.

67. Abbott and Mead also owed a duty to the consuming public in general, and the Plaintiff Parent in particular, to manufacture, sell, and distribute their products in a manner that was merchantable and reasonably suited for their intended use.

68. Abbott and Mead knew that their products would be used to feed premature infants like the Injured Infant and knew (or reasonably should have known) that use of their cow's milk-based products significantly increased the risk of NEC, serious injury, and death, and that such use was therefore unreasonably dangerous to premature infants, not reasonably suited for the use intended, not merchantable, and had risks that exceeded a reasonable buyer's expectations. Nonetheless, they continued to sell and market their defective products as appropriate for premature infants.

69. The Injured Infant ingested Abbott and/or Mead's unreasonably dangerous cow's milk-based products. The risks of feeding those products to the Injured Infant outweighed the benefits. An ordinary consumer would not expect those products to carry a significant risk of serious injury and death from NEC.

70. Abbott and Mead knew (or reasonably should have known) that breast milk-based nutrition did not carry the same risks of NEC, serious injury, and death that their products do.

71. Abbott's and Mead's products contained cow's milk at the time they left the manufacturing facility.

72. Abbott and Mead did not develop a human-milk based product that was safer for premature infants and did not reformulate their products to reduce the risk of NEC, serious injury, and death, even though doing so was economically and technologically feasible and even though pasteurized breast milk was an available alternative.

73. Abbott's and/or Mead's products were fed to the Injured Infant, which caused and/or increased the risk of their NEC and injuries.

74. As a further direct result, the Plaintiff Parent suffered significant emotional distress, loss of income, and/or other harms. Her life has been significantly affected by the Injured Infant's injuries.

WHEREFORE, Plaintiff demands judgment against the Defendant Manufacturers as follows:

- a. For compensatory damages in an amount to be proven at trial and in excess of \$50,000 and this Court's arbitrational limit;
- b. For damages for past, present, and future emotional distress, loss of enjoyment of life, pain and suffering, mental anguish, and other non-economic losses sustained as a result of the Defendants Manufacturers' conduct;
- c. For past, present, and future out-of-pocket costs, lost income and/or lost revenue, and/or lost profits, and/or lost business opportunity, lost earning capacity, and costs related to medical or mental health treatment which have or may be recommended;
- d. For punitive damages in excess of \$50,000 and this Court's arbitrational limit resulting from the Defendant Manufacturers' oppressive, fraudulent, and/or malicious conduct, as permitted by law;
- e. For interest as permitted by law;
- f. For attorney's fees, expenses, and recoverable costs incurred in connection with this action; and
- g. For such other and further relief as the Court deems proper.

**COUNT II: STRICT LIABILITY FOR FAILURE TO WARN
(Against Abbott and Mead)**

75. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.

76. Abbott and Mead, as the manufacturers and/or sellers of the infant products at issue in this litigation, owed a duty to the consuming public in general, and the Plaintiff Parent in particular, to provide adequate warnings or instructions about the dangers and risks associated with the use of

their products with preterm infants, specifically including but not limited to the risk of NEC, serious injury, and death.

77. Abbott's and Mead's duty to warn is part of their general duty to design, manufacture, and sell their infant products in a manner that is reasonably safe for their foreseeable uses. By designing their products with cow's milk-based ingredients, Abbott and Mead undertook a duty to warn of the unreasonable risk of harm posed by those ingredients, specifically including the significantly increased risk of NEC, severe injury, and death. The failure to warn makes the products at issue in this litigation unreasonably dangerous.

78. Specifically, Abbott and Mead breached their duty to warn of the foreseeable risks of the infant products at issue in this litigation because they knew or should have known that their cow's milk-based premature infant products would be fed to premature infants like the Injured Infant, and that their products might cause the Injured Infant to develop NEC, severe injury, or death, yet they failed to provide adequate warnings of those risks. Among other risks, the Defendant Manufacturers:

- a. Failed to warn that cow's milk-based products significantly increase the risk of NEC, severe injury, and death for the Injured Infant; and/or
- b. Failed to warn that cow's milk-based products are unsafe and/or contraindicated for premature infants like the Injured Infant; and/or
- c. Inserted warnings and instructions on their products that are severely inadequate, vague, confusing, and provide a false sense of security in that they warn and instruct specifically on certain conditions, but do not warn of the significantly increased risk of NEC and death; and/or

- d. Failed to insert a large and prominent “black box”-type warning that their cow’s milk-based products are known to significantly increase the risk of NEC and death when compared to breast milk in premature infant; and/or
- e. Failed to disclose well-researched and well-established studies that linked cow’s milk-based products to NEC and death in premature infants; and/or
- f. Failed to insert a warning or instruction to healthcare professionals and other medical staff in the hospital that parents should be provided information necessary to make an informed choice about whether to allow their babies to be fed the Defendant Manufacturers’ products, notwithstanding their substantial risks; and/or
- g. Failed to provide a warning in a method reasonably calculated or expected to reach the parents of newborns, like the Plaintiff Parent; and/or
- h. Failed to provide statistical evidence showing the magnitude of increased risk of NEC in premature infants associated with cow’s milk-based products.

79. Abbott’s and Mead’s products contained cow’s milk at the time they left the manufacturing facility.

80. As a direct and proximate result of the inadequacy of the warnings and the pervasive marketing campaigns suggesting the safety and necessity of the Defendant Manufacturers’ products, the Injured Infant were fed cow’s milk-based products, which caused them to develop NEC.

81. The unwarned-of risks are not of a kind that an ordinary consumer would expect. Had physicians and medical staff known of the extreme risk associated with feeding premature infants cow’s milk-based formula, they would not have fed the Injured Infant those products. Had the

Plaintiff Parent known of the significant risks of feeding the Injured Infant cow's milk-based formula, they would not have allowed such products to be fed to the Injured Infant.

82. As a further direct result, the Plaintiff Parent suffered significant emotional distress, loss of income, and/or other harms. Her life has been significantly affected by the Injured Infant's injuries.

WHEREFORE, Plaintiff demands judgment against the Defendant Manufacturers as follows:

- a. For compensatory damages in an amount to be proven at trial and in excess of \$50,000 and this Court's arbitrational limit;
- b. For damages for past, present, and future emotional distress, loss of enjoyment of life, pain and suffering, mental anguish, and other non-economic losses sustained as a result of the Defendants Manufacturers' conduct;
- c. For past, present, and future out-of-pocket costs, lost income and/or lost revenue, and/or lost profits, and/or lost business opportunity, lost earning capacity, and costs related to medical or mental health treatment which have or may be recommended;
- d. For punitive damages in excess of \$50,000 and this Court's arbitrational limit resulting from the Defendants Manufacturers' oppressive, fraudulent, and/or malicious conduct, as permitted by law;
- e. For interest as permitted by law;
- f. For attorney's fees, expenses, and recoverable costs incurred in connection with this action; and
- g. For such other and further relief as the Court deems proper.

**COUNT III: NEGLIGENCE
(Against Abbott and Mead)**

83. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.

84. Abbott and Mead, as the manufacturers and/or sellers of the products at issue in this litigation, owed a duty to the consuming public in general, and the Plaintiff Parent in particular, to exercise reasonable care to design, test, manufacture, inspect, and distribute a product free of unreasonable risk of harm to users, when such products are used in their intended manner and for their intended purpose.

85. At all times relevant to this action, the Injured Infant's healthcare professionals and medical staff used the products at issue in their intended manner and for their intended purpose.

86. Abbott and Mead, directly or indirectly, negligently, and/or defectively made, created, manufactured, designed, assembled, tested, marketed, sold, and/or distributed the cow's milk-based infant products at issue in this litigation and thereby breached their duty to the general public and the Plaintiff Parent.

87. Specifically, although Abbott and Mead knew or reasonably should have known at the time of production that their cow's milk-based infant products significantly increased the risk of NEC, serious injury, and death, they failed to act in a reasonably prudent manner and breached their duty by:

- a. Failing to warn that cow's milk-based products significantly increase the risk of NEC, severe injury, and death for the Injured Infant; and/or
- b. Failing to warn that cow's milk-based products are unsafe and/or contraindicated for premature infants like the Injured Infant; and/or

- c. Inserting warnings and instructions that are severely inadequate, vague, confusing, and provide a false sense of security in that they warn and instruct specifically on certain conditions, but do not warn of the significantly increased risk of NEC and death; and/or
- d. Failing to insert a large and prominent “black box”-type warning that their cow’s milk-based products are known to significantly increase the risk of NEC and death when compared to breast milk in premature infants; and/or
- e. Failing to provide well-researched and well-established studies that linked cow’s milk-based products to NEC and death in premature infants; and/or
- f. Failing to insert a warning or instruction to healthcare professionals and other medical staff in the hospital that parents should be provided information necessary to make an informed choice about whether to allow their babies to be fed the Defendant Manufacturers’ products, notwithstanding their substantial risks; and/or
- g. Failing to provide a warning in a method reasonably calculated/expected to reach the parents of newborns, like the Plaintiff Parent; and/or
- h. Failing to provide statistical evidence showing the magnitude of increased risk of NEC in premature infants associated with cow’s milk-based products.

88. In addition, although Abbott and Mead knew or reasonably should have known at the time of production that their cow’s milk-based products significantly increased the risk of NEC, serious injury, and death, they failed to act in a reasonably prudent manner and breached their duty by failing to perform the necessary process of data collection, detection, assessment, monitoring, prevention, and reporting or disclosure of adverse outcomes in infants who ingest their products.

89. As a direct and proximate result of the Defendant Manufacturers' failure to act in a reasonably prudent manner and their breach of duty, the Injured Infant was fed cow's milk-based products, which caused and/or increased the risk of their developing NEC.

90. Had Abbott and Mead satisfied their duties to the consuming public in general, the Injured Infant would not have been exposed to their unreasonably dangerous cow's milk-based products.

91. As a further direct result, the Plaintiff Parent suffered significant emotional distress, loss of income, and/or other harms. Her life has been significantly affected by the Injured Infant's injuries.

WHEREFORE, Plaintiff demands judgment against the Defendant Manufacturers as follows:

- a. For compensatory damages in an amount to be proven at trial and in excess of \$50,000 and this Court's arbitrational limit;
- b. For damages for past, present, and future emotional distress, loss of enjoyment of life, pain and suffering, mental anguish, and other non-economic losses sustained as a result of the Defendants Manufacturers' conduct;
- c. For past, present, and future out-of-pocket costs, lost income and/or lost revenue, and/or lost profits, and/or lost business opportunity, lost earning capacity, and costs related to medical or mental health treatment which have or may be recommended;
- d. For punitive damages in excess of \$50,000 and this Court's arbitrational limit resulting from the Defendants Manufacturers' oppressive, fraudulent, and/or malicious conduct, as permitted by law;
- e. For interest as permitted by law;
- f. For attorney's fees, expenses, and recoverable costs incurred in connection with this action; and

g. For such other and further relief as the Court deems proper.

**COUNT IV: INTENTIONAL MISREPRESENTATION
(Against Abbott and Mead)**

92. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.

93. At all times relevant to this action, the Injured Infant consumed the Defendant Manufacturers' products in their intended manner and for their intended purpose.

94. Abbott and Mead, as the manufacturers and/or sellers of the infant products at issue in this litigation, owed a duty to the consuming public in general, and the Plaintiff Parent in particular, to provide truthful, accurate, fulsome information about the risks and benefits of using their products when used in the intended manner and for the intended purpose.

95. Abbott and Mead breached their duty through misrepresentations made to consumers, physicians, and medical staff in their advertising and promotional materials, as described in previous paragraphs and incorporated herein, each of whom were foreseeable and intended recipients of this information.

96. Specifically, upon information and belief, Abbott and Mead made the following false statements of material fact on an ongoing and repeated basis and prior to the time the Injured Infant was fed their products:

- a. That their cow's milk-based products were safe and beneficial for premature infants when they knew or should have known that their products were unreasonably dangerous and cause NEC, serious injury, and death in premature infants; and/or
- b. That their cow's milk-based products were necessary to the growth and nutrition of premature infants, when they knew or should have known that their products were not necessary to achieve adequate growth; and/or

- c. That their products have no serious side effects, when they knew or should have known the contrary to be true; and/or
- d. That cow's milk-based products were safe for premature infants; and/or
- e. That cow's milk-based products were necessary for optimum growth; and/or
- f. That cow's milk-based products were similar or equivalent to breast milk; and/or
- g. That their products were safe and more like breast milk than other infant products and that they had removed the harmful ingredients of cow's milk when, in fact, the cow's milk in their products was still capable of causing NEC, serious injury, and death; and/or
- h. That their products were based on up-to-date science, which made them safe for premature infants; and/or
- i. Omitting the material fact that their products significantly increased the risk of NEC in premature infants.

97. Abbott and Mead knew or reasonably should have known those misrepresentations to be false.

98. The Defendant Manufacturers' misrepresentations were intended to, and in fact did, induce physicians and medical staff, including the Injured Infant's physicians and medical staff, to provide their infant products to babies, including the Injured Infant.

99. The Plaintiff Parent was not aware that these misrepresentations were false and justifiably relied on them. The Defendant Manufacturers' misrepresentations induced the Plaintiff Parent to allow their children to be fed Abbott's and Mead's infant products, in reliance on all the messaging they received about formula feeding, including, directly or indirectly, the Defendant Manufacturers' messaging. Had Abbott and Mead not committed these intentional

misrepresentations, the Injured Infant would not have been exposed to the Defendant Manufacturers' unreasonably dangerous cow's milk-based products.

100. As a direct and proximate result, Abbott's and Mead's products were fed to the Injured Infant, which caused and/or increased risk of their developing NEC and subsequent injuries.

101. As a further direct result, the Plaintiff Parent suffered significant emotional distress, loss of income, and/or other harms. Her life has been significantly affected by the Injured Infant's injuries.

WHEREFORE, Plaintiff demands judgment against the Defendant Manufacturers as follows:

- a. For compensatory damages in an amount to be proven at trial and in excess of \$50,000 and this Court's arbitrational limit;
- b. For damages for past, present, and future emotional distress, loss of enjoyment of life, pain and suffering, mental anguish, and other non-economic losses sustained as a result of the Defendants Manufacturers' conduct;
- c. For past, present, and future out-of-pocket costs, lost income and/or lost revenue, and/or lost profits, and/or lost business opportunity, lost earning capacity, and costs related to medical or mental health treatment which have or may be recommended;
- d. For punitive damages in excess of \$50,000 and this Court's arbitrational limit resulting from the Defendant Manufacturers' oppressive, fraudulent, and/or malicious conduct, as permitted by law;
- e. For interest as permitted by law;
- f. For attorney's fees, expenses, and recoverable costs incurred in connection with this action; and
- g. For such other and further relief as the Court deems proper.

**COUNT V: NEGLIGENT MISREPRESENTATIONS
(Against Abbott and Mead)**

102. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.

103. At all times relevant to this action, the Injured Infant consumed the products at issue in their intended manner and for their intended purpose.

104. Abbott and Mead, as the manufacturers and/or sellers of the products at issue in this litigation, owed a duty to the consuming public in general, and the Plaintiff Parent in particular, to provide truthful, accurate, and complete information about the risks and benefits of using their products when used in the intended manner and for the intended purpose.

105. In the course of their business, Abbott and Mead breached their duty through misrepresentations made to consumers, physicians, and medical staff in their advertising and promotional materials, as described in previous paragraphs and incorporated herein, each of whom were foreseeable recipients of this information.

106. Specifically, upon information and belief, Abbott and Mead made the following false statements of material fact on an ongoing and repeated basis and prior to the time the Injured Infant was fed their products:

- a. That their cow's milk-based products were safe and beneficial for premature infants when they knew or should have known that their products were unreasonably dangerous and cause NEC, serious injury, and death in premature infants; and/or
- b. That their cow's milk-based products were necessary to the growth and nutrition of premature infants, when they knew or should have known that their products were not necessary to achieve adequate growth; and/or

- c. That their products have no serious side effects, when they knew or should have known the contrary to be true; and/or
- d. That cow's milk-based products were safe for premature infants; and/or
- e. That cow's milk-based products were necessary for optimum growth; and/or
- f. That cow's milk-based products were similar or equivalent to breast milk; and/or
- g. That their products were safe and more like breast milk than other infant products and that they had removed the harmful ingredients of cow's milk when, in fact, the cow's milk in their products was still capable of causing NEC, serious injury, and death; and/or
- h. That their products were based on up-to-date science, which made them safe for premature infants; and/or
- i. Omitting the material fact that their products significantly increased the risk of NEC in premature infants.

107. Abbott and Mead were negligent or careless in not determining those representations to be false.

108. The Defendant Manufacturers' misrepresentations were intended to and did in fact induce physicians and medical staff, including the Injured Infant's physicians and medical staff, to provide their products to babies, including the Injured Infant.

109. The Defendant Manufacturers' misrepresentations induced, and were intended to induce, the Plaintiff Parent to allow their child to be fed Abbott's and Mead's infant products, in justifiable reliance on all the messaging they received about formula feeding, including, directly or indirectly, the Defendant Manufacturers' messaging. Had Abbott and Mead not committed these negligent

misrepresentations, the Injured Infant would not have been exposed to their unreasonably dangerous cow's milk-based products.

110. As a direct and proximate result, Abbott's and Mead's products were fed to the Injured Infant, which caused and/or increased of their developing NEC and subsequent injuries.

111. As a further direct result, the Plaintiff Parent suffered significant emotional distress, loss of income, and/or other harms. Her life has been significantly affected by the Injured Infant's injuries.

WHEREFORE, Plaintiff demands judgment against the Defendant Manufacturers as follows:

- a. For compensatory damages in an amount to be proven at trial and in excess of \$50,000 and this Court's arbitrational limit;
- b. For damages for past, present, and future emotional distress, loss of enjoyment of life, pain and suffering, mental anguish, and other non-economic losses sustained as a result of the Defendants Manufacturers' conduct;
- c. For past, present, and future out-of-pocket costs, lost income and/or lost revenue, and/or lost profits, and/or lost business opportunity, lost earning capacity, and costs related to medical or mental health treatment which have or may be recommended;
- d. For punitive damages in excess of \$50,000 and this Court's arbitrational limit resulting from the Defendant Manufacturers' oppressive, fraudulent, and/or malicious conduct, as permitted by law;
- e. For interest as permitted by law;
- f. For attorney's fees, expenses, and recoverable costs incurred in connection with this action; and
- g. For such other and further relief as the Court deems proper.

**COUNT VI: FAILURE TO WARN
(Against Penn Medicine and Pennsylvania Hospital)**

112. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.

113. Penn Medicine and Pennsylvania Hospital as purchaser, supplier, and/or distributor of the products at issue in this litigation, owed a duty to the consuming public in general, and the Plaintiff Parent in particular, to purchase, supply, and distribute products that were free of unreasonable risk of harm when used in their intended manner and for their intended purpose, and/or to formulate, adopt, and enforce adequate rules and policies for the same.

114. At all times relevant to this action, the Injured Infant used the cow's milk-based products purchased, supplied, and/or distributed by Penn Medicine and Pennsylvania Hospital in their intended manner and for their intended purpose.

115. Penn Medicine and Pennsylvania Hospital employed or contracted with the healthcare professionals and medical staff at Pennsylvania Hospital, managing these individuals during their treatment of the Injured Infant.

116. Penn Medicine and Pennsylvania Hospital negligently and recklessly supplied and distributed the Defendant Manufacturers' milk-based infant feeding products to these healthcare professionals and medical staff for use on premature infants, including the Injured Infant.

117. Moreover, at all relevant times, Penn Medicine and Pennsylvania Hospital knowingly authorized the Defendant Manufacturers' sales representatives to market, advertise, distribute, and/or sell their products at Pennsylvania Hospital. The Defendant Manufacturers' sales representatives were encouraged to interact with Pennsylvania Hospital's healthcare professionals and medical staff. These interactions provided the Defendant Manufacturers' sales representatives an opportunity to co-opt Pennsylvania Hospital's healthcare professionals and medical staff into

assisting with the marketing, distribution, and/or sale of the Defendant Manufacturers' unreasonably dangerous products to consumers, such as the Plaintiff Parent.

118. Penn Medicine and Pennsylvania also knowingly allowed the Defendant Manufacturers' sales representatives to routinely misrepresent the risks and benefits of Defendants' products to Pennsylvania Hospital's healthcare professionals and medical staff, including the misrepresentation that premature babies would not grow adequately with human milk and human milk products and that use of donor milk was not advised for premature infants.

119. Penn Medicine and Pennsylvania Hospital knew or reasonably should have known at the time that they acquired, distributed, and supplied the Defendant Manufacturers' cow's milk-based infant products that these products significantly increased the risk of NEC, serious injury, and death.

120. Nonetheless, Penn Medicine and Pennsylvania Hospital acted negligently, recklessly and breached its duty by:

- a. Failing to warn that cow's milk-based products significantly increase the risk of NEC, severe injury, and death in those babies; and/or
- b. Failing to warn that cow's milk-based products are unsafe and/or contraindicated for premature infants like the Injured Infant; and/or
- c. Failing to warn or instruct its healthcare professionals and medical staff on the information that should be provided to parents in order to make an informed choice about whether to allow their babies to be fed the Defendant Manufacturers' products, notwithstanding their substantial risk; and/or

- d. Failing to provide its healthcare professionals and medical staff with the well-researched and well-established studies that link cow's milk-based products to NEC and death in premature infants; and/or
- e. Failing to provide a warning in a method reasonably calculated/expected to reach the parents of newborns; and/or
- f. Failing to provide statistical evidence showing the magnitude of increased risk of NEC in premature infants associated with cow's milk-based products; and/or
- g. Failing to prevent the Defendant Manufacturers' sales representatives from misrepresenting to Pennsylvania Hospital's healthcare professionals and medical staff that premature babies would not grow adequately with human milk and human milk products and that use of donor milk was not advised for premature infants.

121. Reasonable hospitals under the same or similar circumstances would have warned of the above risks, would have instructed their healthcare professionals and medical staff—as well as patients—on the safe use of the Defendant Manufacturers' products, and would have restricted the ability of the Defendant Manufacturers' sales representatives to market the Defendant Manufacturers' unreasonably dangerous products without adequate warning.

122. Penn Medicine and Pennsylvania Hospital knew or reasonably should have known that its medical professionals and the parents of premature infants, including the Plaintiff Parent, would not have realized the risks associated with feeding cow's milk-based formula to premature infants.

123. Had Penn Medicine and Pennsylvania Hospital exercised reasonable care by satisfying its duty to warn its medical providers and patients about the Defendant Manufacturers' unreasonably dangerous products, the Injured Infant would not have been exposed to the Defendant Manufacturers' cow's milk-based products.

124. As a direct and proximate result of Penn Medicine and Pennsylvania Hospital's failure to warn of the danger posed by the Defendant Manufacturers' unreasonably dangerous cow's milk-based products, the Injured Infant was fed the Defendant Manufacturers' cow's milk-based products, which caused and/or increased the risk of developing NEC and significant injuries.

125. As a further direct and proximate result of Penn Medicine and Pennsylvania failure to warn of the Defendant Manufacturers' unreasonably dangerous products, the Plaintiff Parent suffered significant emotional distress, loss of income, and/or other harms. Her life has been significantly affected by the Injured Infant's injuries.

WHEREFORE, Plaintiff demands judgment against Penn Medicine and Pennsylvania Hospital as follows:

- a. For compensatory damages in an amount to be proven at trial and in excess of \$50,000 and this Court's arbitrational limit;
- b. For damages for past, present, and future emotional distress, loss of enjoyment of life, pain and suffering, mental anguish, and other non-economic losses sustained as a result of Penn Medicine's conduct;
- c. For past, present, and future out-of-pocket costs, lost income and/or lost revenue, and/or lost profits, and/or lost business opportunity, lost earning capacity, and costs related to medical or mental health treatment which have or may be recommended;
- d. For punitive damages in excess of \$50,000 and this Court's arbitrational limit resulting from Penn Medicine and Pennsylvania Hospital's oppressive, reckless, and/or malicious conduct, as permitted by law;
- e. For interest as permitted by law;

- f. For attorney's fees, expenses, and recoverable costs incurred in connection with this action; and
- g. For such other and further relief as the Court deems proper.

**COUNT VII: CORPORATE LIABILITY OF HEALTH-CARE PROVIDER
(Against Penn Medicine and Pennsylvania Hospital)**

126. Plaintiff incorporates by references each of the preceding paragraphs as if fully set forth herein.

127. At all relevant times, Penn Medicine and Pennsylvania Hospital owed a duty of care to the Injured Infant to ensure their safety and well-being while the Injured Infant was under the care of Pennsylvania Hospital staff. Specifically, Penn Medicine and Pennsylvania Hospital had a duty to the Injured Infant to formulate, adopt, and enforce adequate rules and policies to ensure quality care for the Injured Infant. Further, Penn Medicine and Pennsylvania Hospital owed a duty to the Injured Infant to oversee its healthcare professionals and medical staff that provided patient care to the Injured Infant.

128. Penn Medicine and Pennsylvania Hospital owed a duty to its patients, and the Injured Infant in particular, to formulate, adopt, and enforce adequate rules and policies for the purchase, supply, distribution, and use of products that were free of unreasonable risk of harm when used in their intended manner and for their intended purpose and ensured quality care for the Injured Infant.

129. At all times relevant to this action, the Injured Infant used the cow's milk-based products purchased, supplied, and/or distributed by Penn Medicine and Pennsylvania Hospital in their intended manner and for their intended purpose.

130. Moreover, at all relevant times, Penn Medicine and Pennsylvania Hospital knowingly authorized the Defendant Manufacturers' sales representatives to market, advertise, distribute,

and/or sell their products at Pennsylvania Hospital. The Defendant Manufacturers' sales representatives were encouraged to interact with Pennsylvania Hospital's healthcare professionals and medical staff. These interactions provided the Defendant Manufacturers' sales representatives an opportunity to co-opt Pennsylvania Hospital's healthcare professionals and medical staff into assisting with the marketing, distribution, and/or sale of the Defendant Manufacturers' unreasonably dangerous products.

131. Penn Medicine and Pennsylvania Hospital also knowingly allowed the Defendant Manufacturers' sales representatives to routinely misrepresent the risks and benefits of Defendants' products to Pennsylvania Hospital's healthcare professionals and medical staff, including the misrepresentation that premature babies would not grow adequately with human milk and human milk products and that use of donor milk was not advised for premature infants.

132. Penn Medicine and Pennsylvania Hospital knew or reasonably should have known at the time that it formulated, adopted, and enforced its rules for the acquisition, distribution, and supply of the Defendant Manufacturers' cow's milk-based infant products, including the access afforded the Defendant Manufacturer's sales representatives, that these products significantly increased the risk of NEC, serious injury, and death for premature infants.

133. Penn Medicine and Pennsylvania Hospital knew or reasonably should have known that its medical professionals and the parents of premature infants, including the Plaintiff Parent, would not have realized the risks associated with feeding cow's milk-based formula to premature infants.

134. Nonetheless, Penn Medicine and Pennsylvania Hospital acted negligently, recklessly and breached its duty by:

- a. Failing to formulate, adopt, and enforce adequate rules and policies that would have restricted the use of cow's milk-based products for feeding premature babies; and/or
- b. Failing to formulate, adopt, and enforce adequate rules and policies that warned the Plaintiff Parent that cow's milk-based products significantly increase the risk of NEC, severe injury, and death in premature babies, like the Injured Infant; and/or
- c. Failing to formulate, adopt, and enforce adequate rules and policies that warned its healthcare professionals and medical staff that cow's milk-based products are unsafe and/or contraindicated for premature babies like the Injured Infant; and/or
- d. Failing to formulate, adopt, and enforce adequate rules and policies to instruct its healthcare professionals and medical staff on the information that should be provided to parents in order to make an informed choice about whether to allow their babies to be fed the Defendant Manufacturers' products, notwithstanding their substantial risk; and/or
- e. Failing to formulate, adopt, and enforce adequate rules and policies to provide its healthcare professionals and medical staff with the well-researched and well-established studies that link cow's milk-based products to NEC and death in premature infants; and/or
- f. Failing to formulate, adopt, and enforce adequate rules and policies to ensure a warning in a method reasonably calculated/expected to reach the parents of newborns, like the Plaintiff Parent; and/or
- g. Failing to formulate, adopt, and enforce adequate rules and policies to prevent the Defendant Manufacturers' sales representative from misrepresenting to

Pennsylvania Hospital's healthcare professionals and medical staff that premature babies would not grow adequately with human milk and human milk products and that use of donor milk was not advised for premature infants; and/or

- h. Failing to establish a donor milk program that was sufficient to meet the needs of the premature babies, like the Injured Infant.

135. A reasonable hospital under the same or similar circumstances would have formulated, adopted, and enforced adequate policies, and rules to restrict the feeding of cow's milk-based products to premature babies, including developing an adequate donor milk program, instructing its healthcare professionals and medical staff on the safe use of Defendants Manufacturers' cow's milk-based products, and restricting the marketing of the Defendant Manufacturers' unreasonably dangerous products to its healthcare professionals, medical staff, and parents of premature infants under its care.

136. Had Penn Medicine and Pennsylvania Hospital exercised reasonable care by satisfying its duty to formulate, adopt, and enforce adequate rules and policies to ensure the quality care of its patients, the Injured Infant would not have been exposed to the Defendant Manufacturers' cow's milk-based products.

137. As a direct and proximate result of Penn Medicine and Pennsylvania Hospital failure to formulate and enforce adequate policies and rules related to the danger posed by the Defendant Manufacturers' unreasonably dangerous cow's milk-based products, the Injured Infant was fed the Defendant Manufacturers' cow's milk-based products, which caused and/or increased the risk of developing NEC and significant injuries.

138. As a further direct and proximate result of Penn Medicine and Pennsylvania Hospital negligent and reckless conduct the Plaintiff Parent suffered significant emotional distress, loss of

income, and/or other harms. Her life has been significantly affected by the Injured Infant's injuries.

139. In the alternative, Penn Medicine and Pennsylvania Hospital owed a duty to its patients, and the Injured Infant in particular, to oversee the practicing healthcare professionals and medical staff that provided the products at issue to infants under Pennsylvania Hospital's care, including the Injured Infant.

140. Penn Medicine and Pennsylvania Hospital employed or contracted with the healthcare professionals and medical staff at Pennsylvania Hospital and was responsible for overseeing those individuals during their treatment of the Injured Infant.

141. Nonetheless, Penn Medicine and Pennsylvania Hospital acted negligently, recklessly and breached its duty by:

- a. Failing to oversee its healthcare professionals and medical staff on their use of cow's milk-based products for feeding premature babies; and/or
- b. Failing to warn or instruct its healthcare professionals and medical staff that cow's milk-based products significantly increase the risk of NEC, severe injury, and death in those babies; and/or
- c. Failing to warn or instruct its healthcare professionals and medical staff that cow's milk-based products are unsafe and/or contraindicated for premature babies like the Injured Infant; and/or
- d. Failing to oversee its healthcare professionals and medical staff to restrict their feeding of cow's milk-based products to premature babies; and/or
- e. Failing to warn or instruct its healthcare professionals and medical staff on the information that should be provided to parents in order to make an informed choice

about whether to allow their babies to be fed the Defendant Manufacturers' products, notwithstanding their substantial risk; and/or

- f. Failing to provide its healthcare professionals and medical staff with the well-researched and well-established studies that link cow's milk-based products to NEC and death in premature infants; and/or
- g. Failing to provide its healthcare professionals and medical staff with warnings about the dangers of the Defendants' Manufacturers products in a method reasonably calculated/expected to reach the parents of newborns; and/or
- h. Failing to provide statistical evidence to its healthcare professionals and medical staff showing the magnitude of increased risk of NEC in premature infants associated with cow's milk-based products; and/or
- i. Failing to oversee its healthcare professionals and medical staff to ensure that the Defendant Manufacturers' sales representatives' misrepresentations that premature babies would not grow adequately with human milk and human milk products and that use of donor milk was not advised for premature infants had not influenced the use and/or misuse of the Defendant Manufacturers' products.

142. A reasonable hospital under the same or similar circumstances would have warned of the above risks, would have instructed its healthcare professionals and medical staff on the safe use of the Defendant Manufacturers' products, and would have restricted the ability of the Defendant Manufacturers' sales representatives to market the Defendant Manufacturers' unreasonably dangerous products without adequate warning.

143. A reasonable hospital under the same or similar circumstances would have overseen and managed its healthcare professionals and medical staff to ensure that they received proper training and updating on the risks associated with feeding cow's milk-based formula to premature infants.

144. Had Penn Medicine and Pennsylvania Hospital exercised reasonable care by satisfying its duty to oversee its healthcare professionals and medical staff who provide patient care, the Injured Infant would not have been exposed to the Defendant Manufacturers' cow's milk-based products.

145. As a direct and proximate result of Penn Medicine and Pennsylvania Hospital's failure to oversee its healthcare professionals and medical staff on the danger posed by the Defendant Manufacturers' unreasonably dangerous cow's milk-based products, the Injured Infant was fed the Defendant Manufacturers' cow's milk-based products, which caused and/or increased the risk of developing NEC and significant injuries.

146. As a further direct and proximate result of Penn Medicine and Pennsylvania Hospital's negligent and reckless conduct, , the Plaintiff Parent suffered significant emotional distress, loss of income, and/or other harms. Her life has been significantly affected by the Injured Infant's injuries.

WHEREFORE, Plaintiff demands judgment against Penn Medicine and Pennsylvania Hospital as follows:

- a. For compensatory damages in an amount to be proven at trial and in excess of \$50,000 and this Court's arbitrational limit;
- b. For damages for past, present, and future emotional distress, loss of enjoyment of life, pain and suffering, mental anguish, and other non-economic losses sustained as a result of Penn Medicine and Pennsylvania Hospital's conduct;

- c. For past, present, and future out-of-pocket costs, lost income and/or lost revenue, and/or lost profits, and/or lost business opportunity, lost earning capacity, and costs related to medical or mental health treatment which have or may be recommended;
- d. For punitive damages in excess of \$50,000 and this Court's arbitrational limit resulting from Penn Medicine's oppressive, fraudulent, and/or malicious conduct, as permitted by law;
- e. For interest as permitted by law;
- f. For attorney's fees, expenses, and recoverable costs incurred in connection with this action; and
- g. For such other and further relief as the Court deems proper.

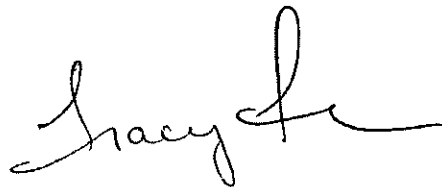
DEMAND FOR JURY TRIAL

147. Plaintiff hereby demands a jury trial for all claims triable.

Dated: March 24, 2022

Respectfully submitted,

ANAPOL WEISS



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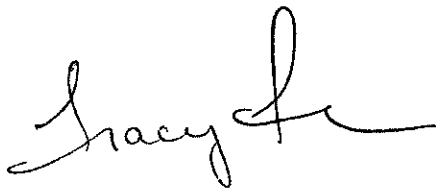
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Attorneys for Plaintiff

CERTIFICATE OF SERVICE

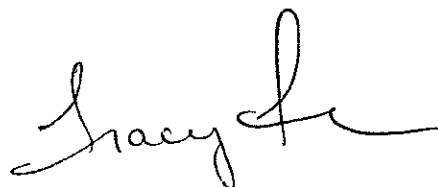
I hereby certify that on March 24, 2022, I electronically filed the foregoing document with the Clerk of the Court using CM/ECF and that the foregoing document is being served on all counsel of record or parties registered to receive CM/ECF Electronic Filings.

A handwritten signature in black ink, appearing to read "Tracy Finken", written over a horizontal line.

Tracy Finken

VERIFICATION

I, the undersigned, Tracy Finken, verify that the statements made in this document are true and correct to the best of my knowledge, information, and belief. I understand that false statements herein are made subject to the penalties of 18 Pa. C.S. §4904, relating to unsworn falsification to authorities.

A handwritten signature in black ink, appearing to read "Tracy Finken", written over a horizontal line.

Tracy Finken

Date: March 24, 2022

KLINE & SPECTER, P.C.

By:

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320927 / 205677

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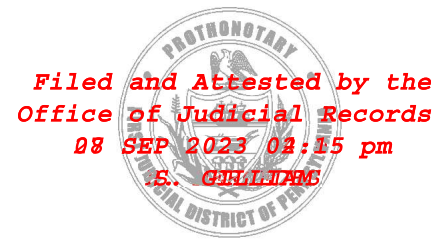
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ALICE STILLS, on her own behalf and as Parent
and Natural Guardian of M.E., a Minor,

Plaintiff,

v.

MEAD JOHNSON & COMPANY, LLC, MEAD
JOHNSON NUTRITION COMPANY, ABBOTT
LABORATORIES, THE TRUSTEES OF THE
UNIVERSITY OF PENNSYLVANIA d/b/a PENN
MEDICINE, and PENNSYLVANIA HOSPITAL OF THE
UNIVERSITY OF PENNSYLVANIA HEALTH SYSTEM
d/b/a PENNSYLVANIA HOSPITAL,

Defendants.

: **IN THE COURT OF COMMON PLEAS**
: **PHILADELPHIA COUNTY**
:
: **CIVIL TRIAL DIVISION**
:
: **MARCH TERM 2022**
: **NO. 2617**

NOTICE TO PLEAD AND DEFEND

NOTICE

You have been sued in court. If you wish to defend against the claims set forth in the following pages, you must take action within twenty (20) days after this complaint and notice are served, by entering a written appearance personally or by attorney and filing in writing with the court your defenses or objections to the claims set forth against you. You are warned that if you fail to do so the case may proceed without you and a judgment may be entered against you by the court without further notice for any money claimed in the complaint or for any other claim or relief requested by the plaintiff. You may lose money or property or other rights important to you.

YOU SHOULD TAKE THIS PAPER TO YOUR LAWYER

ADVISO

Le han demandado a usted en la corte. Si usted quiere defenderse de estas demandas expuestas en las paginas siguientes, usted tiene veinte (20) dias de plazo al partir de la fecha de la demanda y la notificacion. Hace falta asentar una comparencia escrita o en persona o con un abogado y entregar a la corte en forma escrita sus defensas o sus objeciones a las demandas en contra de su persona. Sea avisado que si usted no se defiende, la corte tomara medidas y puede continuar la demanda en contra suya sin previo aviso o notificacion. Ademas, la corte pueda decidir a favor del demandante y requiere que usted cumpla con todas las provisiones de esta demanda. Usted puede perder dinero o sus propiedades u otros derechos importantes para usted.

LLEVE ESTA DEMANDA A UN ABOGADO INMEDIATAMENTE, SI

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Pennsylvania Health System d/b/a Pennsylvania Hospital (collectively “Penn Medicine” or “Pennsylvania Hospital”), together “Defendants.” Plaintiff alleges the following upon personal knowledge as to Plaintiff’s own acts and experiences and upon information and belief, including investigation conducted by Plaintiff’s attorneys, as to all other matters.

I. INTRODUCTION

1. This action arises out of the injuries suffered by a premature infant (the “Injured Infant”) who was given the Defendant Manufacturers’ cow’s milk-based infant feeding products at Pennsylvania Hospital. Pennsylvania Hospital, managed by Penn Medicine, acquired and supplied the Defendant Manufacturers’ products to the Injured Infant and negligently failed to warn of their unreasonably dangerous properties in a reasonable manner. This caused the Injured Infant to develop necrotizing enterocolitis (“NEC”), a life-altering and potentially deadly disease that largely affects premature babies who are given cow’s milk-based feeding products. As a result, the Injured Infant was seriously injured, resulting in long term health effects and accompanying harm to their parent (“the Plaintiff Parent”).

2. Plaintiff brings these causes of action against Defendants to recover for injuries that are the direct and proximate result of the Injured Infant’s consumption of the Defendant Manufacturers’ unreasonably dangerous cow’s milk-based infant feeding products, which were acquired and supplied without adequate warning to the Injured Infant at Pennsylvania Hospital, owned and operated by Penn Medicine.

II. PARTIES

3. Plaintiff Alice Stills is a natural adult person and a resident of Pennsylvania. Ms. Stills is the parent and natural guardian of M.E., a minor. Ms. Stills’s address is 656 N Conestoga Street, Philadelphia, Pennsylvania 19131.

4. Defendant Mead Johnson Nutrition Company is a corporation, incorporated under the laws of the State of Delaware. Its principal place of business is Illinois. Defendant Mead Johnson & Company, LLC, is a limited liability company, organized under the laws of the State of Delaware. Its citizenship is that of its sole member, Mead Johnson Nutrition Company. Defendants Mead Johnson Nutrition Company and Mead Johnson & Company, LLC, (together, “Mead”) are manufacturers of cow’s milk-based infant feeding products and market many of these products under the “Enfamil” brand name.

5. Defendant Abbott Laboratories (“Abbott”) is a corporation, incorporated under the laws of the State of Illinois. Its principal place of business is in Illinois. Abbott is a manufacturer of cow’s milk-based infant feeding products and markets many of its products under the “Similac” brand name.

6. Defendant The Pennsylvania Hospital of the University of Pennsylvania Health System d/b/a Pennsylvania Hospital is a non-profit corporation incorporated and registered to do business under the laws of the Commonwealth of Pennsylvania. Its principal place of business is Philadelphia, Pennsylvania. Pennsylvania Hospital is a registered name of The Pennsylvania Hospital of the University of Pennsylvania Health System. The sole member of The Pennsylvania Hospital of the University of Pennsylvania Health System is The Trustees of the University of Pennsylvania.

7. Defendant The Trustees of the University of Pennsylvania d/b/a Penn Medicine is a non-profit corporation registered to do business in the Commonwealth of Pennsylvania. Its principal place of business is Philadelphia, Pennsylvania. Penn Medicine is a registered name of The Trustees of the University of Pennsylvania.

III. JURISDICTION AND VENUE

8. This Court has jurisdiction in this matter pursuant to 42 Pa. C.S.A. § 931. Defendants conduct authorized business in the Commonwealth of Pennsylvania. They have sufficient minimum contacts with and purposefully avail themselves of the markets of this Commonwealth. This suit arises out of Defendants' forum-related activities, such that the Court of Common Pleas of Philadelphia County's exercise of jurisdiction would be consistent with traditional notions of fair play and substantial justice.

9. Venue is proper in the Court of Common Pleas of Philadelphia County pursuant to Rules 1006(b), 1006(c)(1), and 2179(a) of the Pennsylvania Rules of Civil Procedure because Defendants are corporations or similar entities that regularly conduct business in Philadelphia County, which is also the county where Plaintiff's causes of action arose, and the county where the occurrences took place out of which Plaintiff's causes of action arose.

10. This action is not subject to the Compulsory Arbitration Program of the Court of Common Pleas of Philadelphia County because the amount in controversy, excluding interest and costs, is in excess of \$50,000.

IV. FACTUAL ALLEGATIONS

M.E.'s NEC Diagnosis

11. M.E. was born prematurely at Pennsylvania Hospital in Philadelphia, Pennsylvania on September 28, 2007.

12. At birth, M.E.'s gestational age was approximately 28 weeks and he weighed 907 grams. Upon information and belief, M.E. was fed Similac and/or Enfamil cow's milk-based products by staff at Pennsylvania Hospital after his birth.

13. Upon information and belief, M.E. developed NEC after ingesting Defendant Manufacturers' products.

14. M.E.'s diagnosis of NEC occurred during his course of treatment at Defendant Hospital's NICU. M.E. suffered injuries, including but not limited to, a diagnosis of NEC, treatment with antibiotics and surgery, feeding difficulties, neurological injuries, developmental delays, and growth issues and he continues to suffer other long-term health effects.

***Cow's Milk-Based Feeding Products Are Known to Cause
NEC***

15. NEC is a devastating disease that is the most frequent and lethal gastrointestinal disorder affecting preterm infants. NEC develops when harmful bacteria breach the walls of the intestine, causing portions of the intestine to become inflamed and often to die. Once NEC develops, the condition can progress rapidly from mild feeding intolerance to systemic and fatal sepsis. Up to 30 percent of NEC-diagnosed infants die from the disease.

16. Preterm and low-birth-weight infants are especially susceptible to NEC because of their underdeveloped digestive systems. Extensive scientific research, including numerous randomized controlled trials, has confirmed that cow's milk-based feeding products cause NEC in preterm and low-birth-weight infants, which in turn may lead to other medical complications, surgeries, long-term health problems, and death.

Safer, Nutritionally Superior Alternatives to Cow's Milk-Based Products Exist

17. A range of options are available that allow preterm and low-birth-weight infants to be fed exclusively human milk-based nutrition. For example, in addition to the mother's own milk, an established network delivers pasteurized donor breast milk to hospitals nationwide. Moreover, hospitals have access to shelf-stable formula and fortifiers derived from pasteurized breast milk.

18. A diet based exclusively on breast milk and breast milk fortifiers provides all the nutrition necessary to support premature and low-birth-weight infants without the elevated risk of NEC associated with cow's milk-based products.

19. The Defendant Manufacturers' products not only pose a threat to infants' health, but also displace the breast milk they could otherwise receive. This displacement only increases infants' vulnerability to NEC.

20. Breast milk-based nutrition nourishes infants while creating a significantly lower risk of NEC.

21. At the time the Injured Infant was fed the Defendant Manufacturers' products, the science clearly demonstrated to Defendants that these products cause NEC and greatly increase the likelihood that a baby will develop NEC, leading to severe injury and often death.

22. Despite the scientific consensus that the Defendant Manufacturers' cow's milk-based products present a dire threat to the health and development of preterm infants, the Defendant Manufacturers have made no changes to their products or the products' packaging, guidelines, instructions, or warnings. Instead, they have continued to sell their unreasonably dangerous products. In addition, they incentivize hospitals that know the risks to use their products by providing them to the hospital for free or at a significant discount, in order that vulnerable infants and their families will become accustomed to using their products before discharge. And, in fact, the Defendant Manufacturers offer contracts to hospitals—which the hospitals accept—that actually *prevent* the health care providers from offering alternative products—even safer ones—on pain of risking the hospital's advantageous formula pricing strategy.

Ms. Stills Discovers Her Claim

23. Because of the Defendants' concealment and misrepresentations, described more fully herein, Ms. Stills did not know, and had no reason to know or suspect, that M.E.'s NEC could have been caused by the Defendant Manufacturers' products.

***Despite Exercising Diligence, a Reasonable Investigation Did Not Reveal and
Would Not Have Revealed a Factual Basis Earlier
Because Defendants Hid the Cause of NEC from Ms. Stills***

24. Despite exercising reasonable diligence, Ms. Stills was unable to have made the discovery earlier via a reasonable investigation because the Defendants in this litigation concealed the wrongful cause of M.E.'s injuries.

25. Not one person at Penn Medicine mentioned that the Defendant Manufacturers' formula products could have caused M.E.'s injuries. Penn Medicine's response at the time did not give Ms. Stills any reason to suspect any wrongdoing on the part of the Defendants.

26. Ms. Stills is a layperson with no medical background or training that would have given her any reason to doubt the response she received from her Penn Medicine health care providers at the time.

27. Given that Penn Medicine's health care providers were in charge of the care of her newborn infant, Ms. Stills had no reason to doubt their word.

28. Additionally, the risk of necrotizing enterocolitis was not disclosed on the labeling or packaging of *any* of the Defendant Manufacturers' products.

29. What is more, necrotizing enterocolitis is a disease that can occur in children who are *not* fed the Defendant Manufacturers' products, and the Defendant Manufacturers have worked to mislead parents into a false sense of security about the use of those products. Publicly disseminated materials from each Defendant Manufacturer disguise the role their products play in causing the disease—and affirmatively say, even today, that their products are safe and do not cause NEC. In fact, some publicly disseminated materials from the formula manufacturers even suggest that formula may help *reduce* the risk of this terrible and potentially fatal disease.

30. For example, Abbott’s website stays that “[t]he specific cause of NEC is unknown, but it’s most often seen in very low birth weight premature babies,” and that “about 10% of babies who are born prematurely develop NEC.” The website suggests that “new preliminary studies” suggest for the first time that “NEC prevention may . . . be possible” with the use of human milk oligosaccharides to “dramatically curb intestinal inflammation” and reduce the risk of NEC. Abbott states that these human milk oligosaccharides are found in “certain Similac formulas” although they are “not currently available in Similac’s premature infant formulas.”¹ Likewise, the website for Mead Johnson’s products states that necrotizing enterocolitis is “one of the most common and serious intestinal disease[s] among premature babies.” And it deflects responsibility from Mead Johnson’s products: “Necrotizing enterocolitis happens when tissue in the small or large intestine is injured or inflamed.”²

31. Because of the misleading information distributed by the Defendant Manufacturers, as further detailed below, a reasonable person would not suspect that the Defendant Manufacturers’ products could have caused M.E.’s injuries.

32. Ms. Stills also did not know, and had no reason to know or suspect, that Penn Medicine breached its duty of care by distributing the Defendant Manufacturers’ products to him. Not only was Ms. Stills unaware that the Defendant Manufacturers’ products caused M.E.’s injuries, but the Defendant Manufacturers’ distribution agreements with Penn Medicine—which allowed Penn Medicine to secure sweetheart deals for otherwise expensive premature infant formula in exchange for product placement and access to the hospital staff—were also not public or knowable to Ms.

¹ The Role of HMOs in Reducing NEC, <https://www.nutritionnews.abbott/pregnancy-childhood/prenatal-breastfeeding/the-promising-role-of-hmos-in-reducing-risk-of-nec/> (last visited July 28, 2023).

² Special Feeding Concerns for Preemies, <https://www.enfamil.com/articles/special-feeding-concerns-for-preemies/> (last visited July 29, 2023).

Stills, nor could any reasonable investigation outside of litigation have uncovered the terms of those agreements.

Despite Exercising Reasonable Diligence, the Defendants' Fraudulently Concealed the Risks of NEC from Defendant Manufacturers' Products to Divert, Prevent, and Mislead Plaintiff Regarding the Cause of Her Child's NEC Diagnosis

33. In addition to the averments above, the Defendants have acted in concert to fraudulently convey false and misleading information concerning the risk of NEC, and potentially death, caused by Defendant Manufacturers' preterm infant formula products.

34. The Defendants' actions as set forth herein constitute knowing misrepresentation, omission, suppression, and concealment of material facts, made with the intent that Plaintiff would rely upon such concealment, suppression, or omission, in connection with the use of Defendants' preterm infant products.

35. Plaintiff did not know, and could not learn, the truth concerning the uses, risks and benefits of Defendant Manufacturers' preterm infant products due to Defendants' deliberate misrepresentations and concealment, suppression and omission of material facts and important information regarding the risks of NEC, and potentially death, from the products.

36. Moreover, Defendant Hospital further participated in the intentional concealment—on information and belief, it allowed the Defendant Manufacturers' sales representatives into its hospital to provide samples and free products that did not warn of their serious dangers, and to provide “education” to its NICU staff that was incomplete as to the true risks of feeding their patients the Defendant Manufacturers' products.

37. Additionally, Defendant Hospital failed to inform Ms. Stills that the Defendant Manufacturers' products caused Plaintiff's NEC. As noted above, after learning of Plaintiff's NEC diagnosis, Ms. Stills was understandably concerned about the degrading health of her newborn

infant. But even though Defendant Hospital knew of the increased risk of NEC from formula, it did not disclose that the formula provided to M.E. could increase the risk of NEC to preterm infants. Not one person at the NICU mentioned that the Defendant Manufacturers' formula products could have been the cause of Plaintiff's injuries.

38. Defendant Hospital was aware that the Defendant Manufacturers' products caused NEC in premature infants. Defendant Hospital was also aware that the Defendant Manufacturers did not provide warnings on their products. However, Defendant Hospital did not warn Ms. Taylor of the risks of the products. Instead, and notwithstanding the sweetheart deal Defendant Hospital agreed to in exchange for preterm infant formula at little to no cost, Defendant Hospital repeatedly informed Ms. Stills that it would do everything it could possibly do to keep her infant safe. Though this was clearly not true given the known risks of preterm formula for babies like M.E., it was enough for Ms. Stills to trust that Defendant Hospital was providing preterm formula in the best interest of her child.

39. Defendants' affirmative acts of fraud and concealment, as averred herein, diverted, prevented, and/or mislead Plaintiff from discovering the medical cause of her child's NEC diagnosis.

The Defendant Manufacturers' False and Misleading Marketing Regarding Cow's Milk-Based Infant Products

40. Abbott and Mead have aggressively marketed their cow's milk-based products as medically endorsed and nutritionally equivalent alternatives to breast milk, including prior to the Injured Infant's birth.

41. Abbott's and Mead's marketing approach includes targeting the parents of preterm infants while they are still in the hospital with messages that the Defendant Manufacturers' cow's milk formulas and fortifiers are necessary for the growth and development of their vulnerable children.

Often these tactics implicitly discourage mothers from breastfeeding, which reduces the mother's supply of breast milk. None of the Defendant Manufacturers' marketing materials, including their promotional websites, reference the science showing how significantly their products increase the risk of NEC.

42. Undoubtedly aware of the impact of their advertising, the Defendant Manufacturers, along with other formula manufacturers, are willing to spend massive sums to disseminate their message.

43. Recognizing the abuse and dangers of infant formula marketing, in 1981, the World Health Assembly—the decision-making body of the World Health Organization—developed the International Code of Marketing of Breast-milk Substitutes (“the Code”), which required companies to acknowledge the superiority of breast milk, the negative effect on breastfeeding of introducing partial bottle-feeding, and the difficulty of reversing the decision not to breastfeed. The Code also forbade advertising or other forms of promotion of formula to the general public, as well as providing sample products to mothers or members of their families.

44. While Abbott and Mead acknowledge the Code on their websites and claim to support the effort to encourage mothers to breastfeed for as long as possible, this is little more than lip service. Instead, the Defendant Manufacturers' aggressive marketing exploits new parents' darkest fears—that the nutrition they are supplying to their child will not provide the best chance of survival—while wholly failing to warn that their products come with a significantly increased risk of NEC.

45. For example, Abbott's website, on a page titled “Infant Formula Marketing,” states: “We agree with the World Health Organization that breastfeeding provides the best nutrition for babies, and we support its goal to increase breastfeeding. We also recognize that for infants who aren't breastfed—for medical reasons or otherwise—infant formula is the only appropriate, safe

alternative to meet babies' nutritional needs." This statement ignores the existence of donor milk, as well as human milk-based formula.

46. Abbott markets and sells multiple products specifically targeting preterm and low-birthweight infants, including Liquid Protein Fortifier, Similac NeoSure, Similac Human Milk Fortifiers, Similac Special Care 20, Similac Special Care 24, Similac Special Care 24 High Protein, and Similac Special Care 30. In advertising these products, Abbott emphasizes the products' purported ability to assist underdeveloped babies in reaching their growth targets. For example, on the since-edited webpage regarding Similac NeoSure, Abbott noted: "Your premature baby didn't get her full 9 months in the womb, so her body is working hard to catch up. During her first full year, feed her Similac NeoSure, a nutrient-enriched formula for babies who were born prematurely, and help support her development." Yet, no mention was made of the accompanying significantly increased risk of NEC. At some point, the website was edited to remove this statement. However, upon information and belief, the statement remained on the website until at least December 2020.

47. Mead markets and sells multiple products specifically targeting premature infants, including Enfamil NeuroPro EnfaCare Infant Formula, Enfamil Premature Infant Formula 24 Cal High Protein, Enfamil Premature Infant Formula 30 Cal with Iron, Enfamil Premature Infant Formula 24 Cal with Iron, Enfamil Premature Infant Formula 20 Cal with Iron, Enfamil 24 Cal Infant Formula, and Enfamil Human Milk Fortifier (acidified liquid and powder). In advertising these products, Mead emphasizes the purported similarities between its formula and breast milk, while failing to include any information about the nutritional deficits and dangers that accompany formula use. For example, the since-edited webpage for Enfamil Enfacare stated: "Premature babies fed Enfamil® formulas during the first year have achieved catch-up growth similar to that

of full term, breastfed infants” and noted that Enfamil formulas include “expert-recommended levels of DHA and ARA (important fatty acids found naturally in breast milk) to support brain and eye development.”

48. One Enfamil advertisement, introducing a new product line called Enfamil NeuroPro, is entirely focused on favorably comparing Enfamil’s formula to breast milk, without any mention of the product’s extreme risks. Indeed, the terms “human milk” and “breast milk” are used 13 times in the advertisement, including in such statements as “for decades human milk has inspired the advancements in Enfamil formulas and now through extensive global research, we are taking an even closer look at human milk” and “only Enfamil NeuroPro has a fat blend of MFGM and DHA previously found only in breast milk.” The webpage for the product has made similar manipulative claims, stating “Enfamil is backed by decades of breast milk research and multiple clinical studies” and it claims that “to create our best formulas, we collaborated on some of the most extensive breast milk studies to date[.]”

49. Formula manufacturers have long used their relationships with hospitals and the discharge process to encourage parents to substitute formula for breast milk. They offer free or reduced-cost formula to hospitals for use with infants before discharge. And they offer free formula, coupons, and even entire gift baskets to parents before their infants’ discharge from the NICU or hospital.

50. Through this early targeting, the Defendant Manufacturers create brand loyalty under the guise of a “medical blessing,” in hopes that new parents continue to use formula after they leave the hospital, resulting in increased expense for parents, significantly increased risk for babies, and increased profit for the Defendant Manufacturers. The Defendant Manufacturers’ giveaways and gift baskets send confusing signals to mothers who are simultaneously being encouraged to breastfeed by their healthcare professionals, and they have been shown to negatively impact

breastfeeding rates.

51. Further, when the Defendant Manufacturers recognized a shift in the medical community towards an exclusive breast milk-based diet for premature infants, Abbott developed a product called “Similac Human Milk Fortifier,” and Mead developed “Enfamil Human Milk Fortifier.” These names are misleading in that they suggest that the products are derived from breast milk, when, in fact, they are cow’s milk-based products. The packaging appears as:



52. The Defendant Manufacturers have designed powerful misleading marketing campaigns to deceive parents into believing that: (1) cow’s milk-based products are safe, including for preterm infants; (2) cow’s milk-based products are equal, or even superior, substitutes to breast milk; (3) cow’s milk-based products are necessary for proper growth and development of preterm infants; and (4) physicians consider the Defendant Manufacturers’ cow’s milk-based products to be a first

choice. This marketing scheme is employed despite all Defendants knowing of and failing to warn of the extreme risk of NEC and death that cow's milk-based products pose to preterm infants like the Injured Infant.

53. The Defendant Manufacturers have also designed powerful marketing campaigns to both the general public and health care providers at hospitals like Pennsylvania Hospital. The Defendant Manufacturers know that sales made to hospitals are key drivers of brand loyalty, and thus are a key opportunity to drive better downstream business—*i.e.*, retail purchases by parents after they have left the hospital. On information and belief, the Defendant Manufacturers know that the formula products used in a hospital's NICU are related to getting and keeping the overall hospital contracts. And the Defendant Manufacturers know that, just like any celebrity endorsement, when mothers of newborn infants see medical professionals using a certain brand, the mothers are more likely to continue to purchase that same brand after discharge. The Defendant Manufacturers are thus heavily motivated to ensure that NICU departments are using their products.

54. Abbott and Mead Johnson focus their sales teams and training heavily on hospital NICU departments. They train their sales representatives how to increase the number of babies on their formula, and they emphasize the need to be the dominant formula manufacturer in the NICU so they can own that profitable ground and secure a great return on their substantial investment in NICU formula and other products.

55. To leverage hospitals' NICUs and secure babies in the hospital and at retail, the Manufacturer Defendants pull out all the stops to convince hospitals, including Defendant Hospital, to purchase their products. For example: Abbott and Mead Johnson provide samples of their products to hospitals for free.

56. On information and belief, to get the hospitals on board with supplying their formula for premature infants, Abbott and Mead Johnson work with hospitals to secure contracts that have special pricing discounts if a certain level of the formula-fed babies in the hospital receive just that one manufacturer's products; similar to a restaurant being a Coke or Pepsi restaurant. And notwithstanding the increased risk of the Defendant Manufacturers' products for the hospitals' most fragile patients—the preterm infants—the decision makers at these hospitals seek out these types of contracts to better the hospitals' own bottom lines.

57. On information and belief, Abbott and Mead Johnson also seek promises and/or assurances that the full range of health care providers at the hospitals, including the nurse practitioners and other staff who would pull the infant formula off the shelf, are grabbing the respective company's own formula products to give to the preterm infants. The goal of this tactic was to ensure that the Defendant Manufacturers and key people at the hospital would be sending a shared message that the preterm infant formula products were safe and without risk, even though that is not what the science said.

58. Prior to M.E.'s birth, Abbott sent sales representatives to Defendant Hospital. Those sales representatives provided information about Abbott's products to Defendant Hospital's staff via conversations, presentations, and written pamphlets. This information indicated that Abbott's products were safe to give to preterm infants like M.E. Abbott maintains call logs that detail which sales representatives visited the hospitals, which days they visited, and which products they discussed. These sales representatives did not disclose that Abbott's products could cause NEC in preterm infants.

59. Prior to M.E.'s birth, Mead Johnson sent sales representatives to Defendant Hospital. Those sales representatives provided information about Mead Johnson's products to Defendant

Hospital's staff via conversations, presentations, and written pamphlets. This information indicated that Mead Johnson's products were safe to give to preterm infants like M.E. Mead Johnson maintains call logs that detail which sales representatives visited the hospitals, which days they visited, and which products they discussed. These sales representatives did not disclose that Mead Johnson's products could cause NEC in preterm infants.

60. Mead Johnson and Abbott believed and intended that the misrepresentations that its sale representatives shared with Defendant Hospital would be used to make feeding decisions for preterm infants like M.E.

The Defendant Manufacturers' Inadequate Warnings

61. Although Mead promotes an aggressive marketing campaign designed to convince parents that its cow's milk-based products are safe and necessary for the growth of a premature infant, the product is in fact extremely dangerous for premature infants. Enfamil products significantly increase the chances of a premature infant developing potentially fatal NEC.

62. The Enfamil products Mead markets specifically for premature infants are commercially available at retail locations and online. No prescription is necessary.

63. Despite knowing of the risk of NEC, the packaging of Mead's products does not warn of the significantly increased risk of NEC (and resulting medical conditions, and/or death) associated with Mead's products, or of the magnitude of this increased risk. Mead likewise did not provide instructions or guidance for how to avoid NEC.

64. Mead cites no medical literature or research to guide the use of its products.

65. Despite knowing of the risk of NEC, Mead did not warn of the significantly increased risk of NEC (and resulting medical conditions, and/or death) associated with its products, or of the magnitude of this increased risk. Mead likewise did not provide instructions or guidance for how to avoid NEC.

66. Mead deceived the public, parents, physicians, other medical professionals, and medical staff into believing that Enfamil products were a safe and necessary alternative, supplement and/or substitute to breast milk.

67. Mead Johnson failed to provide, and continues to fail to provide, a full accounting of the risk of NEC as documented, by underrepresenting and misrepresenting the risk to the public and the medical community.

68. Despite knowing that its products were being fed to premature infants, often without the parents' informed consent, Mead failed to require or recommend that medical professionals inform parents of the significant risk of NEC or to require that parental consent be obtained prior to the products being fed to their babies. Like Mead, Abbott promotes an aggressive marketing campaign designed to make parents believe that its products are safe and necessary for the growth of premature infants, despite the products in fact being extremely dangerous for premature infants. Abbott's products significantly increase the chances of a premature infant getting potentially fatal NEC.

69. The products Abbott markets specifically for premature infants are available at retail locations and online. No prescription is necessary.

70. Despite knowing of the risk of NEC, Abbott did not warn of the significantly increased risk of NEC (and resulting medical conditions, and/or death) associated with its products, or of the magnitude of this increased risk. Abbott likewise did not provide instructions or guidance for how to avoid NEC.

71. Abbott deceived the public, parents, physicians, other medical professionals, and medical staff into believing that its products were a safe and necessary alternative, supplement and/or substitute to breast milk.

72. Despite knowing of studies documenting an increased risk of NEC from its products, Abbott did not act to make parents or the medical community aware of those risks, and instead took steps to conceal or prevent those risks from becoming public. Despite knowing that its products were being fed to premature infants, often without the parents' informed consent, Abbott failed to require or recommend that medical professionals inform parents of the significant risk of NEC or to require that parental consent be obtained prior to the products being fed to their babies.

Penn Medicine's Failure to Warn

73. On information and belief, Penn Medicine, which operates Pennsylvania Hospital, was aware of the significantly increased risk of NEC and death associated with providing Abbott's and Mead's cow's milk-based products to its premature infant patients. It knew or should have known that feeding these cow's milk-based products can cause NEC in premature infants who otherwise would not have developed this devastating condition. However, instead of warning of the dangers, or supplying breast milk-based feeding products to preterm infants like the Injured Infant, Penn Medicine has continued to source, distribute, and supply the Defendant Manufacturers' products in its hospitals without any adequate warning.

74. To that end, Penn Medicine has participated in studies designed to increase the use of donor milk while, at the same time, reducing formula feeding in neonates. The University of Pennsylvania School of Nursing, an affiliate of Penn Medicine, has conducted extensive research into the risks associated with feeding formula to premature infants. It recently partnered with the National Institute of Nursing Research to publish clinical determinations based on its experience "changing hospital systems and influencing policy," and its findings were unequivocal:

This is what we know about the science of human milk: it reduces the risk of necrotizing enterocolitis, reduces the risk of infection, [and] creates greater enteral feed tolerance and more rapid weaning from intravenous nutrition. . . .

Other Penn Medicine research has similarly concluded that "[h]uman milk decreases the incidence

and severity of . . . necrotizing enterocolitis (NEC).”

75. Penn Medicine also purports to adhere to the tenets of the “Baby Friendly Hospital Initiative,” which seeks to increase rates of breastfeeding initiation, exclusivity, and diet duration. The “Baby Friendly Hospital Initiative” specifically targets a reduction in the rates of NEC in preterm infants by encouraging implementation of exclusive breast milk diets among new mothers. Although Pennsylvania Hospital has maintained its “Baby Friendly” designation for years, it has not eliminated or restricted the use of formula or fortifier for preterm infants in its hospitals.

76. Finally, medical providers and staff at Penn Medicine have acknowledged the risks associated with providing the Defendant Manufacturers’ cow’s milk-based products to premature infant patients instead of breast milk-based nutrition. In an internal newsletter from 2012 touting donor milk programs, Penn Medicine acknowledged the benefits of a human milk-based diet, quoting a staff lactation consultant:

Donor milk is not inexpensive. It costs about \$4.25 per ounce, but the return on investment is huge. “Preemies given mother’s milk get discharged three to four days sooner and also have a six to 10 times lower risk of getting a gastrointestinal complication called necrotizing enterocolitis,” Carpenter said, adding that the infection can cost up to \$250,000 to treat. The average cost to provide a preemie with donor milk: \$125.

77. These statements demonstrate that Penn Medicine knew or should have known of the high increased risk of NEC for premature infants posed by the Defendant Manufacturers’ products.

78. Although Penn Medicine knew or should have known of the serious danger of the Defendant Manufacturers’ products, it has continued to purchase, supply, and distribute these products to preterm infants without providing full and adequate warnings of the attendant risks to parents, healthcare professionals, and other medical staff at its relevant facilities. As a result, the Injured Infant was fed the Defendant Manufacturers’ cow’s milk-based products at Pennsylvania

Hospital, causing their injuries. This occurred even though hospitals across the country, including Pennsylvania Hospital, warn and obtain consent from parents before providing other safer forms of nutrition, such as donor breast milk.

79. Penn Medicine's failure to warn of the risks posed by the Defendant Manufacturers' products is entrenched (and compounded) by the financial benefits it accrues from its relationships with the Defendant Manufacturers. On information and belief, it has received the Defendant Manufacturers' cow's milk-based products for free and/or at a significant discount, and has granted their sales representatives access to its healthcare professionals and medical staff. These sales representatives have provided deceptive information that Penn Medicine reasonably knew or should have known would ultimately reach parents through those staff. This arrangement dovetails with the Defendant Manufacturers' own marketing strategies" and use of salespersons.

Safer Alternative Designs

80. The Defendant Manufacturers' cow's milk-based products made specifically for premature infants are unreasonably unsafe for those infants. The Defendant Manufacturers could have used pasteurized breast milk instead of cow's milk in their products, which would have produced a safer product.

81. Prolacta Bioscience manufactures and sells breast milk-based feeding products, specifically designed for preterm infants, which contain no cow's milk. This alternative design provides all the necessary nutrition for growth and development that cow's milk-based products provide, without the same unreasonably dangerous and deadly effects.

82. On information and belief, Abbott and Mead were aware of the significantly increased risk of NEC and death associated with their cow's milk-based products, and instead of warning of the dangers, or removing them altogether, Abbott and Mead have continued to use cow's milk as the

foundation of their products.

CAUSES OF ACTION
COUNT I: STRICT LIABILITY FOR DESIGN DEFECT
(Against Abbott and Mead)

83. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.

84. Abbott and Mead, as the manufacturers and/or sellers of the products at issue in this litigation, owed a duty to the consuming public in general, and the Plaintiff Parent in particular, to manufacture, sell, and distribute their products in a manner that was not unreasonably dangerous.

85. Abbott and Mead also owed a duty to the consuming public in general, and the Plaintiff Parent in particular, to manufacture, sell, and distribute their products in a manner that was merchantable and reasonably suited for their intended use.

86. Abbott and Mead knew that their products would be used to feed premature infants like the Injured Infant and knew (or reasonably should have known) that use of their cow's milk-based products significantly increased the risk of NEC, serious injury, and death, and that such use was therefore unreasonably dangerous to premature infants, not reasonably suited for the use intended, not merchantable, and had risks that exceeded a reasonable buyer's expectations. Nonetheless, they continued to sell and market their defective products as appropriate for premature infants.

87. The Injured Infant ingested Abbott and/or Mead's unreasonably dangerous cow's milk-based products. The risks of feeding those products to the Injured Infant outweighed the benefits. An ordinary consumer would not expect those products to carry a significant risk of serious injury and death from NEC.

88. Abbott and Mead knew (or reasonably should have known) that breast milk-based nutrition did not carry the same risks of NEC, serious injury, and death that their products do.

89. Abbott's and Mead's products contained cow's milk at the time they left the manufacturing facility.

90. Abbott and Mead did not develop a human-milk based product that was safer for premature infants and did not reformulate their products to reduce the risk of NEC, serious injury, and death, even though doing so was economically and technologically feasible and even though pasteurized breast milk was an available alternative.

91. Abbott's and/or Mead's products were fed to the Injured Infant, which caused and/or increased the risk of their NEC and injuries.

92. As a further direct result, the Plaintiff Parent suffered significant emotional distress, loss of income, and/or other harms. Her life has been significantly affected by the Injured Infant's injuries.

WHEREFORE, Plaintiff demands judgment against the Defendant Manufacturers, individually, jointly and severally, as follows:

- a. For compensatory damages in an amount to be proven at trial and in excess of \$50,000 and this Court's arbitrational limit;
- b. For damages for past, present, and future emotional distress, loss of enjoyment of life, pain and suffering, mental anguish, and other non-economic losses sustained as a result of the Defendants Manufacturers' conduct;
- c. For past, present, and future out-of-pocket costs, lost income and/or lost revenue, and/or lost profits, and/or lost business opportunity, lost earning capacity, and costs related to medical or mental health treatment which have or may be recommended;

- d. For punitive damages in excess of \$50,000 and this Court's arbitral limit resulting from the Defendant Manufacturers' oppressive, fraudulent, and/or malicious conduct, as permitted by law;
- e. For interest as permitted by law;
- f. For attorney's fees, expenses, and recoverable costs incurred in connection with this action; and
- g. For such other and further relief as the Court deems proper.

**COUNT II: STRICT LIABILITY FOR FAILURE TO WARN
(Against Abbott and Mead)**

93. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.

94. Abbott and Mead, as the manufacturers and/or sellers of the infant products at issue in this litigation, owed a duty to the consuming public in general, and the Plaintiff Parent in particular, to provide adequate warnings or instructions about the dangers and risks associated with the use of their products with preterm infants, specifically including but not limited to the risk of NEC, serious injury, and death.

95. Abbott's and Mead's duty to warn is part of their general duty to design, manufacture, and sell their infant products in a manner that is reasonably safe for their foreseeable uses. By designing their products with cow's milk-based ingredients, Abbott and Mead undertook a duty to warn of the unreasonable risk of harm posed by those ingredients, specifically including the significantly increased risk of NEC, severe injury, and death. The failure to warn makes the products at issue in this litigation unreasonably dangerous.

96. Specifically, Abbott and Mead breached their duty to warn of the foreseeable risks of the infant products at issue in this litigation because they knew or should have known that their

cow's milk-based premature infant products would be fed to premature infants like the Injured Infant, and that their products might cause the Injured Infant to develop NEC, severe injury, or death, yet they failed to provide adequate warnings of those risks. Among other risks, the Defendant Manufacturers:

- a. Failed to warn that cow's milk-based products significantly increase the risk of NEC, severe injury, and death for the Injured Infant; and/or
- b. Failed to warn that cow's milk-based products are unsafe and/or contraindicated for premature infants like the Injured Infant; and/or
- c. Inserted warnings and instructions on their products that are severely inadequate, vague, confusing, and provide a false sense of security in that they warn and instruct specifically on certain conditions, but do not warn of the significantly increased risk of NEC and death; and/or
- d. "Black box"-type warning that their cow's milk-based products are known to significantly increase the risk of NEC and death when compared to breast milk in premature infant; and/or
- e. Failed to disclose well-researched and well-established studies that linked cow's milk-based products to NEC and death in premature infants; and/or
- f. Failed to insert a warning or instruction to healthcare professionals and other medical staff in the hospital that parents should be provided information necessary to make an informed choice about whether to allow their babies to be fed the Defendant Manufacturers' products, notwithstanding their substantial risks; and/or
- g. Failed to provide a warning in a method reasonably calculated or expected

to reach the parents of newborns, like the Plaintiff Parent; and/or

- h. Failed to provide statistical evidence showing the magnitude of increased risk of NEC in premature infants associated with cow's milk-based products.

97. Abbott's and Mead's products contained cow's milk at the time they left the manufacturing facility.

98. As a direct and proximate result of the inadequacy of the warnings and the pervasive marketing campaigns suggesting the safety and necessity of the Defendant Manufacturers' products, the Injured Infant were fed cow's milk-based products, which caused and/or increased risk of their developing NEC.

99. The unwarned-of risks are not of a kind that an ordinary consumer would expect. Had physicians and medical staff known of the extreme risk associated with feeding premature infants cow's milk-based formula, they would not have fed the Injured Infant those products. Had the Plaintiff Parent known of the significant risks of feeding the Injured Infant cow's milk-based formula, they would not have allowed such products to be fed to the Injured Infant.

100. As a further direct result, the Plaintiff Parent suffered significant emotional distress, loss of income, and/or other harms. Her life has been significantly affected by the Injured Infant's injuries.

WHEREFORE, Plaintiff demands judgment against the Defendant Manufacturers, individually, jointly and severally, as follows:

- a. For compensatory damages in an amount to be proven at trial and in excess of \$50,000 and this Court's arbitrational limit;
- b. For damages for past, present, and future emotional distress, loss of

enjoyment of life, pain and suffering, mental anguish, and other non-economic losses sustained as a result of the Defendants Manufacturers' conduct;

- c. For past, present, and future out-of-pocket costs, lost income and/or lost revenue, and/or lost profits, and/or lost business opportunity, lost earning capacity, and costs related to medical or mental health treatment which have or may be recommended;
- d. For punitive damages in excess of \$50,000 and this Court's arbitral limit resulting from the Defendants Manufacturers' oppressive, fraudulent, and/or malicious conduct, as permitted by law;
- e. For interest as permitted by law;
- f. For attorney's fees, expenses, and recoverable costs incurred in connection with this action; and
- g. For such other and further relief as the Court deems proper.

**COUNT III: NEGLIGENCE
(Against Abbott and Mead)**

101. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.

102. Abbott and Mead, as the manufacturers and/or sellers of the products at issue in this litigation, owed a duty to the consuming public in general, and the Plaintiff Parent in particular, to exercise reasonable care to design, test, manufacture, inspect, and distribute a product free of unreasonable risk of harm to users, when such products are used in their intended manner and for their intended purpose.

103. At all times relevant to this action, the Injured Infant's healthcare professionals and medical

staff used the products at issue in their intended manner and for their intended purpose.

104. Abbott and Mead, directly or indirectly, negligently, and/or defectively made, created, manufactured, designed, assembled, tested, marketed, sold, and/or distributed the cow's milk-based infant products at issue in this litigation and thereby breached their duty to the general public and the Plaintiff Parent.

105. Specifically, although Abbott and Mead knew or reasonably should have known at the time of production that their cow's milk-based infant products significantly increased the risk of NEC, serious injury, and death, they failed to act in a reasonably prudent manner and breached their duty by:

- a. Failing to warn that cow's milk-based products significantly increase the risk of NEC, severe injury, and death for the Injured Infant; and/or
- b. Failing to warn that cow's milk-based products are unsafe and/or contraindicated for premature infants like the Injured Infant; and/or
- c. Inserting warnings and instructions that are severely inadequate, vague, confusing, and provide a false sense of security in that they warn and instruct specifically on certain conditions, but do not warn of the significantly increased risk of NEC and death; and/or
- d. Failing to insert a large and prominent "black box"-type warning that their cow's milk-based products are known to significantly increase the risk of NEC and death when compared to breast milk in premature infants; and/or
- e. Failing to provide well-researched and well-established studies that linked cow's milk-based products to NEC and death in premature infants; and/or
- f. Failing to insert a warning or instruction to healthcare professionals and

other medical staff in the hospital that parents should be provided information necessary to make an informed choice about whether to allow their babies to be fed the Defendant Manufacturers' products, notwithstanding their substantial risks; and/or

- g. Failing to provide a warning in a method reasonably calculated/expected to reach the parents of newborns, like the Plaintiff Parent; and/or
- h. Failing to provide statistical evidence showing the magnitude of increased risk of NEC in premature infants associated with cow's milk-based products.

106. In addition, although Abbott and Mead knew or reasonably should have known at the time of production that their cow's milk-based products significantly increased the risk of NEC, serious injury, and death, they failed to act in a reasonably prudent manner and breached their duty by failing to perform the necessary process of data collection, detection, assessment, monitoring, prevention, and reporting or disclosure of adverse outcomes in infants who ingest their products.

107. As a direct and proximate result of the Defendant Manufacturers' failure to act in a reasonably prudent manner and their breach of duty, the Injured Infant was fed cow's milk-based products, which caused and/or increased the risk of their developing NEC.

108. Had Abbott and Mead satisfied their duties to the consuming public in general, the Injured Infant would not have been exposed to their unreasonably dangerous cow's milk-based products.

109. As a further direct result, the Plaintiff Parent suffered significant emotional distress, loss of income, and/or other harms. Her life has been significantly affected by the Injured Infant's injuries.

WHEREFORE, Plaintiff demands judgment against the Defendant Manufacturers,

individually, jointly and severally, as follows:

- a. For compensatory damages in an amount to be proven at trial and in excess of \$50,000 and this Court's arbitrational limit;
- b. For damages for past, present, and future emotional distress, loss of enjoyment of life, pain and suffering, mental anguish, and other non-economic losses sustained as a result of the Defendants Manufacturers' conduct;
- c. For past, present, and future out-of-pocket costs, lost income and/or lost revenue, and/or lost profits, and/or lost business opportunity, lost earning capacity, and costs related to medical or mental health treatment which have or may be recommended;
- d. For punitive damages in excess of \$50,000 and this Court's arbitrational limit resulting from the Defendants Manufacturers' oppressive, fraudulent, and/or malicious conduct, as permitted by law;
- e. For interest as permitted by law;
- f. For attorney's fees, expenses, and recoverable costs incurred in connection with this action; and
- g. For such other and further relief as the Court deems proper.

**COUNT IV: INTENTIONAL MISREPRESENTATION
(Against Abbott and Mead)**

110. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.

111. At all times relevant to this action, the Injured Infant consumed the Defendant Manufacturers' products in their intended manner and for their intended purpose.

112. Abbott and Mead, as the manufacturers and/or sellers of the infant products at issue in this litigation, owed a duty to the consuming public in general, and the Plaintiff Parent in particular, to provide truthful, accurate, fulsome information about the risks and benefits of using their products when used in the intended manner and for the intended purpose.

113. Abbott and Mead breached their duty through misrepresentations made to consumers, physicians, and medical staff in their advertising and promotional materials, as described in previous paragraphs and incorporated herein, each of whom were foreseeable and intended recipients of this information.

114. Specifically, upon information and belief, Abbott and Mead made the following false statements of material fact on an ongoing and repeated basis and prior to the time the Injured Infant was fed their products:

- a. That their cow's milk-based products were safe and beneficial for premature infants when they knew or should have known that their products were unreasonably dangerous and cause NEC, serious injury, and death in premature infants; and/or
- b. That their cow's milk-based products were necessary to the growth and nutrition of premature infants, when they knew or should have known that their products were not necessary to achieve adequate growth; and/or
- c. That their products have no serious side effects, when they knew or should have known the contrary to be true; and/or
- d. That cow's milk-based products were safe for premature infants; and/or
- e. That cow's milk-based products were necessary for optimum growth; and/or
- f. That cow's milk-based products were similar or equivalent to breast milk;

and/or

- g. That their products were safe and more like breast milk than other infant products and that they had removed the harmful ingredients of cow's milk when, in fact, the cow's milk in their products was still capable of causing NEC, serious injury, and death; and/or
- h. That their products were based on up-to-date science, which made them safe for premature infants; and/or
- i. Omitting the material fact that their products significantly increased the risk of NEC in premature infants.

115. Abbott and Mead had actual knowledge, or, at a minimum, a reckless indifference, to whether the aforementioned misrepresentations were false. The Defendant Manufacturers' misrepresentations were intended to, and in fact did, mislead physicians and medical staff, including the Injured Infant's physicians and medical staff, to provide their infant products to babies, including the Injured Infant.

116. The Plaintiff Parent was not aware that these misrepresentations were false and justifiably relied on them. The Defendant Manufacturers' misrepresentations induced the Plaintiff Parent to allow their children to be fed Abbott's and Mead's infant products, in reliance on all the messaging they received about formula feeding, including, directly or indirectly, the Defendant Manufacturers' messaging. Had Abbott and Mead not committed these intentional misrepresentations, the Injured Infant would not have been exposed to the Defendant Manufacturers' unreasonably dangerous cow's milk-based products.

117. As a direct and proximate result, Abbott's and Mead's products were fed to the Injured Infant, which caused and/or increased risk of their developing NEC and subsequent injuries.

118. As a further direct result, the Plaintiff Parent suffered significant emotional distress, loss of income, and/or other harms. Her life has been significantly affected by the Injured Infant's injuries.

WHEREFORE, Plaintiff demands judgment against the Defendant Manufacturers, individually, jointly and severally, as follows:

- a. For compensatory damages in an amount to be proven at trial and in excess of \$50,000 and this Court's arbitrational limit;
- b. For damages for past, present, and future emotional distress, loss of enjoyment of life, pain and suffering, mental anguish, and other non-economic losses sustained as a result of the Defendants Manufacturers' conduct;
- c. For past, present, and future out-of-pocket costs, lost income and/or lost revenue, and/or lost profits, and/or lost business opportunity, lost earning capacity, and costs related to medical or mental health treatment which have or may be recommended;
- d. For punitive damages in excess of \$50,000 and this Court's arbitrational limit resulting from the Defendant Manufacturers' oppressive, fraudulent, and/or malicious conduct, as permitted by law;
- e. For interest as permitted by law;
- f. For attorney's fees, expenses, and recoverable costs incurred in connection with this action; and
- g. For such other and further relief as the Court deems proper.

**COUNT V: NEGLIGENT MISREPRESENTATIONS
(Against Abbott and Mead)**

119. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.

120. At all times relevant to this action, the Injured Infant consumed the products at issue in their intended manner and for their intended purpose.

121. Abbott and Mead, as the manufacturers and/or sellers of the products at issue in this litigation, owed a duty to the consuming public in general, and the Plaintiff Parent in particular, to provide truthful, accurate, and complete information about the risks and benefits of using their products when used in the intended manner and for the intended purpose.

122. In the course of their business, Abbott and Mead breached their duty through misrepresentations made to consumers, physicians, and medical staff in their advertising and promotional materials, as described in previous paragraphs and incorporated herein, each of whom were foreseeable recipients of this information.

123. Specifically, upon information and belief, Abbott and Mead made the following false statements of material fact on an ongoing and repeated basis and prior to the time the Injured Infant was fed their products:

- a. That their cow's milk-based products were safe and beneficial for premature infants when they knew or should have known that their products were unreasonably dangerous and cause NEC, serious injury, and death in premature infants; and/or
- b. That their cow's milk-based products were necessary to the growth and nutrition of premature infants, when they knew or should have known that their products were not necessary to achieve adequate growth; and/or
- c. That their products have no serious side effects, when they knew or should

have known the contrary to be true; and/or

- d. That cow's milk-based products were safe for premature infants; and/or
- e. That cow's milk-based products were necessary for optimum growth; and/or
- f. That cow's milk-based products were similar or equivalent to breast milk; and/or
- g. That their products were safe and more like breast milk than other infant products and that they had removed the harmful ingredients of cow's milk when, in fact, the cow's milk in their products was still capable of causing NEC, serious injury, and death; and/or
- h. That their products were based on up-to-date science, which made them safe for premature infants; and/or
- i. Omitting the material fact that their products significantly increased the risk of NEC in premature infants.

124. Abbott and Mead were negligent or careless in not determining those representations to be false.

125. The Defendant Manufacturers' misrepresentations were intended to and did in fact induce physicians and medical staff, including the Injured Infant's physicians and medical staff, to provide their products to babies, including the Injured Infant.

126. The Defendant Manufacturers' misrepresentations induced, and were intended to induce, the Plaintiff Parent to allow their child to be fed Abbott's and Mead's infant products, in justifiable reliance on all the messaging they received about formula feeding, including, directly or indirectly, the Defendant Manufacturers' messaging. Had Abbott and Mead not committed these negligent misrepresentations, the Injured Infant would not have been exposed to their unreasonably

dangerous cow's milk-based products.

127. As a direct and proximate result, Abbott's and Mead's products were fed to the Injured Infant, which caused and/or increased of their developing NEC and subsequent injuries.

128. As a further direct result, the Plaintiff Parent suffered significant emotional distress, loss of income, and/or other harms. Her life has been significantly affected by the Injured Infant's injuries.

WHEREFORE, Plaintiff demands judgment against the Defendant Manufacturers, individually, jointly and severally, as follows:

- a. For compensatory damages in an amount to be proven at trial and in excess of \$50,000 and this Court's arbitrational limit;
- b. For damages for past, present, and future emotional distress, loss of enjoyment of life, pain and suffering, mental anguish, and other non-economic losses sustained as a result of the Defendants Manufacturers' conduct;
- c. For past, present, and future out-of-pocket costs, lost income and/or lost revenue, and/or lost profits, and/or lost business opportunity, lost earning capacity, and costs related to medical or mental health treatment which have or may be recommended;
- d. For punitive damages in excess of \$50,000 and this Court's arbitrational limit resulting from the Defendant Manufacturers' oppressive, fraudulent, and/or malicious conduct, as permitted by law;
- e. For interest as permitted by law;
- f. For attorney's fees, expenses, and recoverable costs incurred in connection

with this action; and

g. For such other and further relief as the Court deems proper.

**COUNT VI: FAILURE TO WARN
(Against Penn Medicine and Pennsylvania Hospital)**

129. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.

130. Penn Medicine and Pennsylvania Hospital as purchaser, supplier, and/or distributor of the products at issue in this litigation, owed a duty to the consuming public in general, and the Plaintiff Parent in particular, to purchase, supply, and distribute products that were free of unreasonable risk of harm when used in their intended manner and for their intended purpose, and/or to formulate, adopt, and enforce adequate rules and policies for the same.

131. At all times relevant to this action, the Injured Infant used the cow's milk-based products purchased, supplied, and/or distributed by Penn Medicine and Pennsylvania Hospital in their intended manner and for their intended purpose.

132. Penn Medicine and Pennsylvania Hospital employed or contracted with the healthcare professionals and medical staff at Pennsylvania Hospital, managing these individuals during their treatment of the Injured Infant.

133. Penn Medicine and Pennsylvania Hospital negligently, outrageously, and recklessly supplied and distributed the Defendant Manufacturers' milk-based infant feeding products to these healthcare professionals and medical staff for use on premature infants, including the Injured Infant.

134. Moreover, at all relevant times, Penn Medicine and Pennsylvania Hospital knowingly authorized the Defendant Manufacturers' sales representatives to market, advertise, distribute, and/or sell their products at Pennsylvania Hospital. The Defendant Manufacturers' sales

representatives were encouraged to interact with Pennsylvania Hospital's healthcare professionals and medical staff. These interactions provided the Defendant Manufacturers' sales representatives an opportunity to co-opt Pennsylvania Hospital's healthcare professionals and medical staff into assisting with the marketing, distribution, and/or sale of the Defendant Manufacturers' unreasonably dangerous products to consumers, such as the Plaintiff Parent.

135. Penn Medicine and Pennsylvania also knowingly, and intentionally, allowed the Defendant Manufacturers' sales representatives to routinely misrepresent the risks and benefits of Defendants' products to Pennsylvania Hospital's healthcare professionals and medical staff, including the misrepresentation that premature babies would not grow adequately with human milk and human milk products and that use of donor milk was not advised for premature infants.

136. Penn Medicine and Pennsylvania Hospital knew or reasonably should have known at the time that they acquired, distributed, and supplied the Defendant Manufacturers' cow's milk-based infant products that these products significantly increased the risk of NEC, serious injury, and death.

137. Nonetheless, Penn Medicine and Pennsylvania Hospital acted negligently, outrageously, and recklessly, and breached its duty by:

- a. Failing to warn that cow's milk-based products significantly increase the risk of NEC, severe injury, and death in those babies; and/or
- b. Failing to warn that cow's milk-based products are unsafe and/or contraindicated for premature infants like the Injured Infant; and/or
- c. Failing to warn or instruct its healthcare professionals and medical staff on the information that should be provided to parents in order to make an informed choice about whether to allow their babies to be fed the Defendant

Manufacturers' products, notwithstanding their substantial risk; and/or

- d. Failing to provide its healthcare professionals and medical staff with the well- researched and well-established studies that link cow's milk-based products to NEC and death in premature infants; and/or
- e. Failing to provide a warning in a method reasonably calculated/expected to reach the parents of newborns; and/or
- f. Failing to provide statistical evidence showing the magnitude of increased risk of NEC in premature infants associated with cow's milk-based products; and/or
- g. Failing to prevent the Defendant Manufacturers' sales representatives from misrepresenting to Pennsylvania Hospital's healthcare professionals and medical staff that premature babies would not grow adequately with human milk and human milk products and that use of donor milk was not advised for premature infants.

138. Reasonable hospitals under the same or similar circumstances would have warned of the above risks, would have instructed their healthcare professionals and medical staff—as well as patients—on the safe use of the Defendant Manufacturers' products, and would have restricted the ability of the Defendant Manufacturers' sales representatives to market the Defendant Manufacturers' unreasonably dangerous products without adequate warning.

139. Penn Medicine and Pennsylvania Hospital knew or reasonably should have known that its medical professionals and the parents of premature infants, including the Plaintiff Parent, would not have realized the risks associated with feeding cow's milk-based formula to premature infants.

140. Had Penn Medicine and Pennsylvania Hospital exercised reasonable care by satisfying its

duty to warn its medical providers and patients about the Defendant Manufacturers' unreasonably dangerous products, the Injured Infant would not have been exposed to the Defendant Manufacturers' cow's milk-based products.

141. As a direct and proximate result of Penn Medicine and Pennsylvania Hospital's failure to warn of the danger posed by the Defendant Manufacturers' unreasonably dangerous cow's milk-based products, the Injured Infant was fed the Defendant Manufacturers' cow's milk-based products, which caused and/or increased the risk of developing NEC and significant injuries.

142. As a further direct and proximate result of Penn Medicine and Pennsylvania Hospital's failure to warn of the Defendant Manufacturers' unreasonably dangerous products, the Plaintiff Parent suffered significant emotional distress, loss of income, and/or other harms. Her life has been significantly affected by the Injured Infant's injuries.

WHEREFORE, Plaintiff demands judgment against Penn Medicine and Pennsylvania Hospital, individually, jointly and severally, as follows:

- a. For compensatory damages in an amount to be proven at trial and in excess of \$50,000 and this Court's arbitrational limit;
- b. For damages for past, present, and future emotional distress, loss of enjoyment of life, pain and suffering, mental anguish, and other non-economic losses sustained as a result of Penn Medicine's conduct;
- c. For past, present, and future out-of-pocket costs, lost income and/or lost revenue, and/or lost profits, and/or lost business opportunity, lost earning capacity, and costs related to medical or mental health treatment which have or may be recommended;
- d. For punitive damages in excess of \$50,000 and this Court's arbitrational

limit resulting from Penn Medicine and Pennsylvania Hospital's oppressive, outrageous, reckless, and/or malicious conduct, as permitted by law;

- e. For interest as permitted by law;
- f. For attorney's fees, expenses, and recoverable costs incurred in connection with this action; and
- g. For such other and further relief as the Court deems proper.

**COUNT VII: CORPORATE LIABILITY OF HEALTH-CARE PROVIDER
(Against Penn Medicine and Pennsylvania Hospital)**

143. Plaintiff incorporates by references each of the preceding paragraphs as if fully set forth herein.

144. At all relevant times, Penn Medicine and Pennsylvania Hospital owed a duty of care to the Injured Infant to ensure their safety and well-being while the Injured Infant was under the care of Pennsylvania Hospital staff. Specifically, Penn Medicine and Pennsylvania Hospital had a duty to the Injured Infant to formulate, adopt, and enforce adequate rules and policies to ensure quality care for the Injured Infant. Further, Penn Medicine and Pennsylvania Hospital owed a duty to the Injured Infant to oversee its healthcare professionals and medical staff that provided patient care to the Injured Infant.

145. Penn Medicine and Pennsylvania Hospital owed a duty to its patients, and the Injured Infant in particular, to formulate, adopt, and enforce adequate rules and policies for the purchase, supply, distribution, and use of products that were free of unreasonable risk of harm when used in their intended manner and for their intended purpose and ensured quality care for the Injured Infant.

146. At all times relevant to this action, the Injured Infant used the cow's milk-based products purchased, supplied, and/or distributed by Penn Medicine and Pennsylvania Hospital in their

intended manner and for their intended purpose.

147. Moreover, at all relevant times, Penn Medicine and Pennsylvania Hospital knowingly authorized the Defendant Manufacturers' sales representatives to market, advertise, distribute, and/or sell their products at Pennsylvania Hospital. The Defendant Manufacturers' sales representatives were encouraged to interact with Pennsylvania Hospital's healthcare professionals and medical staff. These interactions provided the Defendant Manufacturers' sales representatives an opportunity to co-opt Pennsylvania Hospital's healthcare professionals and medical staff into assisting with the marketing, distribution, and/or sale of the Defendant Manufacturers' unreasonably dangerous products.

148. Penn Medicine and Pennsylvania Hospital also knowingly allowed the Defendant Manufacturers' sales representatives to routinely misrepresent the risks and benefits of Defendants' products to Pennsylvania Hospital's healthcare professionals and medical staff, including the misrepresentation that premature babies would not grow adequately with human milk and human milk products and that use of donor milk was not advised for premature infants.

149. Penn Medicine and Pennsylvania Hospital knew or reasonably should have known at the time that it formulated, adopted, and enforced its rules for the acquisition, distribution, and supply of the Defendant Manufacturers' cow's milk-based infant products, including the access afforded the Defendant Manufacturer's sales representatives, that these products significantly increased the risk of NEC, serious injury, and death for premature infants.

150. Penn Medicine and Pennsylvania Hospital knew or reasonably should have known that its medical professionals and the parents of premature infants, including the Plaintiff Parent, would not have realized the risks associated with feeding cow's milk-based formula to premature infants.

151. Nonetheless, Penn Medicine and Pennsylvania Hospital acted negligently, outrageously,

and recklessly, and breached its duty by:

- a. Failing to formulate, adopt, and enforce adequate rules and policies that would have restricted the use of cow's milk-based products for feeding premature babies; and/or
- b. Failing to formulate, adopt, and enforce adequate rules and policies that warned the Plaintiff Parent that cow's milk-based products significantly increase the risk of NEC, severe injury, and death in premature babies, like the Injured Infant; and/or
- c. Failing to formulate, adopt, and enforce adequate rules and policies that warned its healthcare professionals and medical staff that cow's milk-based products are unsafe and/or contraindicated for premature babies like the Injured Infant; and/or
- d. Failing to formulate, adopt, and enforce adequate rules and policies to instruct its healthcare professionals and medical staff on the information that should be provided to parents in order to make an informed choice about whether to allow their babies to be fed the Defendant Manufacturers' products, notwithstanding their substantial risk; and/or
- e. Failing to formulate, adopt, and enforce adequate rules and policies to provide its healthcare professionals and medical staff with the well-researched and well-established studies that link cow's milk-based products to NEC and death in premature infants; and/or
- f. Failing to formulate, adopt, and enforce adequate rules and policies to ensure a warning in a method reasonably calculated/expected to reach the

parents of newborns, like the Plaintiff Parent; and/or

- g. Failing to formulate, adopt, and enforce adequate rules and policies to prevent the Defendant Manufacturers' sales representative from misrepresenting to Pennsylvania Hospital's healthcare professionals and medical staff that premature babies would not grow adequately with human milk and human milk products and that use of donor milk was not advised for premature infants; and/or
- h. Failing to establish a donor milk program that was sufficient to meet the needs of the premature babies, like the Injured Infant.

152. A reasonable hospital under the same or similar circumstances would have formulated, adopted, and enforced adequate policies, and rules to restrict the feeding of cow's milk-based products to premature babies, including developing an adequate donor milk program, instructing its healthcare professionals and medical staff on the safe use of Defendants Manufacturers' cow's milk-based products, and restricting the marketing of the Defendant Manufacturers' unreasonably dangerous products to its healthcare professionals, medical staff, and parents of premature infants under its care.

153. Had Penn Medicine and Pennsylvania Hospital exercised reasonable care by satisfying its duty to formulate, adopt, and enforce adequate rules and policies to ensure the quality care of its patients, the Injured Infant would not have been exposed to the Defendant Manufacturers' cow's milk-based products.

154. As a direct and proximate result of Penn Medicine and Pennsylvania Hospital failure to formulate and enforce adequate policies and rules related to the danger posed by the Defendant Manufacturers' unreasonably dangerous cow's milk-based products, the Injured Infant was fed the

Defendant Manufacturers' cow's milk-based products, which caused and/or increased the risk of developing NEC and significant injuries.

155. As a further direct and proximate result of Penn Medicine and Pennsylvania Hospital negligent, reckless, and outrageous conduct the Plaintiff Parent suffered significant emotional distress, loss of income, and/or other harms. Her life has been significantly affected by the Injured Infant's injuries.

156. In the alternative, Penn Medicine and Pennsylvania Hospital owed a duty to its patients, and the Injured Infant in particular, to oversee the practicing healthcare professionals and medical staff that provided the products at issue to infants under Pennsylvania Hospital's care, including the Injured Infant.

157. Penn Medicine and Pennsylvania Hospital employed or contracted with the healthcare professionals and medical staff at Pennsylvania Hospital and was responsible for overseeing those individuals during their treatment of the Injured Infant.

158. Nonetheless, Penn Medicine and Pennsylvania Hospital acted negligently, recklessly, and outrageously breached its duty by:

- a. Failing to oversee its healthcare professionals and medical staff on their use of cow's milk-based products for feeding premature babies; and/or
- b. Failing to warn or instruct its healthcare professionals and medical staff that cow's milk-based products significantly increase the risk of NEC, severe injury, and death in those babies; and/or
- c. Failing to warn or instruct its healthcare professionals and medical staff that cow's milk-based products are unsafe and/or contraindicated for premature babies like the Injured Infant; and/or

- d. Failing to oversee its healthcare professionals and medical staff to restrict their feeding of cow's milk-based products to premature babies; and/or
- e. Failing to warn or instruct its healthcare professionals and medical staff on the information that should be provided to parents in order to make an informed choice about whether to allow their babies to be fed the Defendant Manufacturers' products, notwithstanding their substantial risk; and/or
- f. Failing to provide its healthcare professionals and medical staff with the well- researched and well-established studies that link cow's milk-based products to NEC and death in premature infants; and/or
- g. Failing to provide its healthcare professionals and medical staff with warnings about the dangers of the Defendants' Manufacturers products in a method reasonably calculated/expected to reach the parents of newborns; and/or
- h. Failing to provide statistical evidence to its healthcare professionals and medical staff showing the magnitude of increased risk of NEC in premature infants associated with cow's milk-based products; and/or
- i. Failing to oversee its healthcare professionals and medical staff to ensure that the Defendant Manufacturers' sales representatives' misrepresentations that premature babies would not grow adequately with human milk and human milk products and that use of donor milk was not advised for premature infants had not influenced the use and/or misuse of the Defendant Manufacturers' products.

159. A reasonable hospital under the same or similar circumstances would have warned of the

above risks, would have instructed its healthcare professionals and medical staff on the safe use of the Defendant Manufacturers' products, and would have restricted the ability of the Defendant Manufacturers' sales representatives to market the Defendant Manufacturers' unreasonably dangerous products without adequate warning.

160. A reasonable hospital under the same or similar circumstances would have overseen and managed its healthcare professionals and medical staff to ensure that they received proper training and updating on the risks associated with feeding cow's milk-based formula to premature infants.

161. Had Penn Medicine and Pennsylvania Hospital exercised reasonable care by satisfying its duty to oversee its healthcare professionals and medical staff who provide patient care, the Injured Infant would not have been exposed to the Defendant Manufacturers' cow's milk-based products.

162. As a direct and proximate result of Penn Medicine and Pennsylvania Hospital's failure to oversee its healthcare professionals and medical staff on the danger posed by the Defendant Manufacturers' unreasonably dangerous cow's milk-based products, the Injured Infant was fed the Defendant Manufacturers' cow's milk-based products, which caused and/or increased the risk of developing NEC and significant injuries.

163. As a further direct and proximate result of Penn Medicine and Pennsylvania Hospital's negligent and reckless conduct, the Plaintiff Parent suffered significant emotional distress, loss of income, and/or other harms. Her life has been significantly affected by the Injured Infant's injuries.

WHEREFORE, Plaintiff demands judgment against Penn Medicine and Pennsylvania Hospital, individually, jointly and severally, as follows:

- a. For compensatory damages in an amount to be proven at trial and in excess of \$50,000 and this Court's arbitrational limit;

- b. For damages for past, present, and future emotional distress, loss of enjoyment of life, pain and suffering, mental anguish, and other non-economic losses sustained as a result of Penn Medicine and Pennsylvania Hospital's conduct;
- c. For past, present, and future out-of-pocket costs, lost income and/or lost revenue, and/or lost profits, and/or lost business opportunity, lost earning capacity, and costs related to medical or mental health treatment which have or may be recommended;
- d. For punitive damages in excess of \$50,000 and this Court's arbitrational limit resulting from Penn Medicine's oppressive, fraudulent, and/or malicious conduct, as permitted by law;
- e. For interest as permitted by law;
- f. For attorney's fees, expenses, and recoverable costs incurred in connection with this action; and
- g. For such other and further relief as the Court deems proper.

DEMAND FOR JURY TRIAL

164. Plaintiff hereby demands a jury trial for all claims triable.

Dated: 9/8/2023

Respectfully submitted,

KLINE & SPECTER, P.C.

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